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1                   UNITED STATES DISTRICT COURT  
 2                   FOR THE NORTHERN DISTRICT OF OHIO  
 3                   EASTERN DIVISION  
 4  
 5               IN RE: NATIONAL                   )  
 6               PRESCRIPTION                   ) MDL No. 2804  
 7               OPIATE LITIGATION           )  
 8               ) Case No.  
 9               ) 1:17-MD-2804  
 10              )  
 11             THIS DOCUMENT RELATES   ) Hon. Dan A.  
 12             TO ALL CASES               ) Polster  
 13  
 14                   WEDNESDAY, APRIL 24, 2019  
 15  
 16                   HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER  
 17                   CONFIDENTIALITY REVIEW  
 18                   - - -  
 19                   Videotaped deposition of Anna  
 20                   Lembke, M.D., held at the offices of Lieff  
 21                   Cabraser Heimann & Bernstein, LLP, 275  
 22                   Battery Street, 29th floor, San Francisco,  
 23                   California, commencing at 8:07 a.m., on the  
 24                   above date, before Carrie A. Campbell,  
 25                   Registered Diplomate Reporter and Certified  
 26                   Realtime Reporter.

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1	VIDEOPHOTOGRAPHER:	We are now on the record. My name is David Kim.
2		I'm a videographer for Golkow
3		Litigation Services.
4		
5		Today's date is April 24, 2019,
6		and the time is 8:07 a.m.
7		This video deposition is being
8		held in San Francisco, California, in
9		the matter of National Prescription
10		Opiate Litigation, MDL Number 2804 for
11		the US District Court, the Northern
12		District of Ohio, Eastern Division.
13		The deponent is Anna Lembke.
14		Counsel will be noted on the
15		stenographic record.
16		The court reporter is Carrie
17		Campbell and will now swear in the
18		witness.
19		
20		ANNA LEMBKE, M.D.,
21		of lawful age, having been first duly sworn
22		to tell the truth, the whole truth and
23		nothing but the truth, deposes and says on
24		behalf of the Defendants, as follows:
25		

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1		DIRECT EXAMINATION
2		QUESTIONS BY MR. TSAI:
3	Q.	Good morning.
4	A.	Good morning.
5	Q.	Diving right in, to begin with,
6		I just wanted to confirm, are you board
7		certified in anesthesiology, pain medicine or
8		hospice or palliative medicine?
9	A.	No.
10	Q.	Can you explain to the jury
11		what it means to be board certified in a
12		specialized type of medical practice?
13	A.	To be board certified in a
14		specialized type of medical practice means to
15		have received a certain level of training and
16		sit for an exam and passed that exam such
17		that you receive the certification of that
18		specialty.
19	Q.	And can you explain to the
20		jury, what does it mean to complete a
21		residence or a fellowship in a specialized
22		field of medical practice?
23	A.	To complete a residency or
24		fellowship in a specialized field of medical
25		practice means to have spent a certain amount

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1 of time devoted to specifically studying that  
 2 specialty.  
 3 Q. Have you completed any  
 4 residencies or fellowships in anesthesiology,  
 5 pain medicine or hospice and palliative  
 6 medicine?

7 A. No, I have not.

8 Q. In an article you wrote, you  
 9 described yourself as an academic  
 10 psychiatrist.

11 Do you recall writing that  
 12 article on your CV?

13 MR. ARBITBLIT: Do you have a  
 14 copy of it, Counsel?

15 MR. TSAI: I do not. It's  
 16 listed on her CV.

17 QUESTIONS BY MR. TSAI:

18 Q. Do you recall authoring an  
 19 article called "A Friday in the Life of a  
 20 Academic Psychiatrist"?

21 A. Yes, I do.

22 Q. And that was in the journal  
 23 called Academic Psychiatry?

24 A. Yes.

25 Q. Is it accurate to say that you

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1 would hold yourself out as a psychiatrist as  
 2 opposed to a pain management physician or an  
 3 anesthesiologist?  
 4 MR. ARBITBLIT: Object to form.  
 5 THE WITNESS: I would disagree  
 6 with that statement because I do hold  
 7 myself out as having expertise in the  
 8 field of pain management, but not  
 9 anesthesiology, per se.

10 QUESTIONS BY MR. TSAI:

11 Q. How many hours have you spent  
 12 treating patients in palliative care, for  
 13 example, for their individual pain needs?

14 A. I have not worked in a  
 15 palliative care setting.

16 Q. How many patients have you  
 17 diagnosed with chronic pain as another  
 18 example?

19 A. I have diagnosed many patients  
 20 with chronic pain over the years. I've been  
 21 in practice for more than 20 years, seen  
 22 approximately 40,000 patients over my career.  
 23 I couldn't tell the exact number that I've  
 24 diagnosed with chronic pain, but if I had to  
 25 put a ballpark estimate, I would say

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1 something on the order of 50 percent of my  
 2 patients have some kind of chronic pain  
 3 diagnosis.

4 Q. What is the total number of  
 5 patients you've treated for their individual  
 6 pain needs as opposed to addiction associated  
 7 with surgeries or cancer?

8 MR. ARBITBLIT: Object to form.

9 THE WITNESS: It's difficulty  
 10 for me to put an exact number on that.

11 The majority of patients that I treat  
 12 for their pain needs also have some  
 13 sort of co-occurring mental health  
 14 disorder, but pain is a priority in  
 15 the overall treatment plan of those  
 16 patients.

17 QUESTIONS BY MR. TSAI:

18 Q. So just to be clear, in your  
 19 practice, you engage in primary diagnoses of  
 20 patients who are complaining of pain and  
 21 deciding how to treat their pain needs?

22 MR. ARBITBLIT: Objection.

23 THE WITNESS: Yes.

24 QUESTIONS BY MR. TSAI:

25 Q. What is the total number of

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1 peer-reviewed research studies or articles  
 2 you've authored in the field of  
 3 anesthesiology, pain medicine or hospice and  
 4 palliative medicine?

5 A. I've authored two peer-reviewed  
 6 articles in pain medicine journals, but I  
 7 have written more broadly on the issue of  
 8 pain vis-à-vis the opioid epidemic, and so  
 9 that more broad area would include more of my  
 10 publications.

11 Q. And focusing on the two  
 12 articles in Pain Medicine journals, what were  
 13 the subject matters of those two articles?

14 A. The subject matter of those two  
 15 articles in Pain Medicine journals had to do  
 16 with perioperative management of opioid  
 17 agonist treatments such as buprenorphine and  
 18 methadone.

19 Q. Who retained you as a  
 20 testifying witness in this case?

21 A. Lieff Cabraser Heimann &  
 22 Bernstein.

23 Q. And do you know who they  
 24 represent?

25 A. They represent the MDL.

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1 Q. Can you be more specific?  
 2 A. They represent the plaintiffs  
 3 in this case.  
 4 Q. And who are the plaintiffs in  
 5 this case?  
 6 A. The plaintiffs are the counties  
 7 and other entities who have been harmed as a  
 8 result of the opioid epidemic.  
 9 Q. Which counties?  
 10 A. There are too many counties  
 11 to -- I guess the bellwether counties would  
 12 be Cuyahoga and Summit Counties in Ohio.

13 Q. Have you ever prescribed opioid  
 14 medications?  
 15 A. Yes.  
 16 Q. Since when?  
 17 A. I prescribe opioid medications  
 18 on a weekly basis.  
 19 Q. So when did you start  
 20 prescribing opioid medications?  
 21 A. Since I obtained a DEA license.  
 22 Q. And when was that?  
 23 A. That was in 2000, 2001.  
 24 Q. Approximately how many patients  
 25 do you believe you've prescribed opioid

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1 medications to?  
 2 A. It's difficult for me to put a  
 3 number on that. I've been prescribing opioid  
 4 medications since I became a practicing  
 5 physician, and in recent years, I prescribed  
 6 more opioid medication in the treatment of  
 7 opioid use disorder.  
 8 Q. Other than opioid use disorder,  
 9 have you prescribed opioid medications for  
 10 any other condition or indication?  
 11 A. Yes, I have. In the general  
 12 practice of medicine through my career, I  
 13 have prescribed other opioid medications.  
 14 Q. What conditions or indications?  
 15 A. Typically pain conditions.  
 16 Q. When you prescribe opioid  
 17 medications to your patients, do you weigh  
 18 the risks and benefits based on your  
 19 individual patients' medical histories and  
 20 conditions?  
 21 A. Yes, of course.  
 22 Q. Do you have any degrees in  
 23 epidemiology?  
 24 A. No.  
 25 Q. Can you explain to the jury

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1 what epidemiology means?  
 2 A. Epidemiology is the study of  
 3 the progression of disease through a  
 4 population.  
 5 Q. Did you yourself actually  
 6 conduct any of the epidemiological research  
 7 cited in your report regarding factors  
 8 associated with the opioid crisis?  
 9 A. Yes, I did.  
 10 Q. And can you explain what  
 11 research you conducted?  
 12 A. I conducted research regarding  
 13 who was prescribing opioids in this country  
 14 as well as who is prescribing buprenorphine  
 15 for the treatment of opioid use disorder,  
 16 which is relevant to the opioid epidemic more  
 17 broadly.  
 18 Q. And what was the information  
 19 upon which you conducted your research?  
 20 A. It was based on Medicare -- a  
 21 Medicare database from 2013.  
 22 Q. Did you calculate or formulate  
 23 any of your own regression models or  
 24 statistical analyses in this case?  
 25 A. No, I did not.

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1 Q. Okay. Other than the Medicare  
 2 database, did you conduct any of your own  
 3 epidemiological analysis of any data in this  
 4 case specific to the -- strike that.  
 5 Other than the Medicare  
 6 database, did you conduct any original  
 7 epidemiological analysis of any data in this  
 8 case?  
 9 A. Yes, I did.  
 10 Q. What data?  
 11 A. Qualitative data that I  
 12 collected in preparation for writing my book,  
 13 "Drug Dealer, MD: How Doctors Were Duped,  
 14 Patients Got Hooked, and Why It's So Hard to  
 15 Stop."  
 16 Q. And what do you mean by  
 17 qualitative data in connection with writing  
 18 your book?  
 19 A. Interviews that I conducted  
 20 with patients and health care providers in an  
 21 attempt to understand the progression of the  
 22 opioid epidemic in our population.  
 23 Q. Okay. And other than  
 24 conducting interviews in connection with  
 25 writing your book, did you conduct any

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1 quantitative analysis in connection with  
 2 that?  
 3 A. No.  
 4 Q. If you were asked to design an  
 5 epidemiological study and statistically  
 6 analyze the data results for submission to a  
 7 peer-reviewed journal, would you ask for  
 8 help, or would you do that all by yourself?  
 9 MR. ARBITBLIT: Objection.

10 Compound.

11 QUESTIONS BY MR. TSAI:

12 Q. You can answer.  
 13 A. So I don't hold myself out as a  
 14 biostatistician. I work with others who have  
 15 expertise in that area and together we  
 16 collaboratively think about the important  
 17 questions and interpret the data, so I would  
 18 be intimately involved in that process, but I  
 19 would not be conducting the statistical  
 20 analysis by myself.

21 Q. What is the total amount of  
 22 peer-reviewed research studies or articles  
 23 you've authored in the field of epidemiology?

24 A. I feel like I answered that  
 25 question before.

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1 Q. What is your answer?  
 2 MR. ARBITBLIT: Object. Asked  
 3 and answered.  
 4 THE WITNESS: I feel I answered  
 5 that before.

6 QUESTIONS BY MR. TSAI:

7 Q. What is your answer?  
 8 MR. ARBITBLIT: You really want  
 9 to do that? You want to make her go  
 10 back and scroll and find the answer  
 11 she gave you when you asked her about  
 12 that before?

13 QUESTIONS BY MR. TSAI:

14 Q. I'm just wondering what do you  
 15 consider to be an epidemiological study that  
 16 you have authored?

17 A. Well, epidemiologic --  
 18 epidemiology is the study of progression of a  
 19 disease in a population, and I have spent the  
 20 last approximately 20 years studying the  
 21 progression of the disease of opioid  
 22 dependence and addiction in the population.  
 23 And I've written widely about that and I have  
 24 numerous publications, which are in my CV,  
 25 and I have my book "Drug Dealer, MD: How

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1 Doctors Were Duped, Patients Got Hooked, and  
 2 Why It's So Hard to Stop."  
 3 MR. TSAI: I'll respectfully  
 4 move to strike.

5 QUESTIONS BY MR. TSAI:

6 Q. I'll ask you, have you  
 7 conducted or designed any controlled  
 8 epidemiological studies yourself?

9 A. I did answer that question.

10 Q. And what is your answer?

11 A. Well, I already --

12 MR. ARBITBLIT: It's a  
 13 different question.

14 THE WITNESS: It's a  
 15 different --

16 MR. ARBITBLIT: It's a  
 17 different question.

18 THE WITNESS: Okay. So I have  
 19 published two articles on prescribing  
 20 of opioids in this country, which is  
 21 relevant to the problem of the spread  
 22 of the opioid epidemic in this  
 23 country.

24 QUESTIONS BY MR. TSAI:

25 Q. And in those two articles that

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1 you singled out, did you conduct any kind of  
 2 regression analysis or statistical  
 3 significance calculation, multi-variate  
 4 analysis, or were they more qualitative?  
 5 MR. ARBITBLIT: Objection.

6 Compound.

7 THE WITNESS: So those were  
 8 quantitative analyses, which I did in  
 9 collaboration with my biostatistician  
 10 coauthors.

11 QUESTIONS BY MR. TSAI:

12 Q. Okay. And your coauthors who  
 13 were in the field of biostatistics, were they  
 14 the ones who conducted the quantitative  
 15 analysis?

16 A. My coauthors are not  
 17 exclusively in the field of biostatistics,  
 18 but one of the coauthors has expertise in  
 19 that area and did the quantitative analysis.

20 Q. So you yourself did not do the  
 21 quantitative analysis?

22 A. That is correct.

23 Q. Have you ever taught any  
 24 courses in the field of epidemiology?

25 A. I teach on a regular basis to

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1 medical students, residents and practicing  
 2 physicians on the spread of the opioid  
 3 epidemic in the United States, and in that  
 4 sense I have taught courses on epidemiology,  
 5 yes.

6 Q. Other than that qualitative  
 7 sense, do you teach any courses in the field  
 8 of epidemiology, per se?

9 MR. ARBITBLIT: Objection.

10 Argumentative. Asked and answered.

11 THE WITNESS: I feel like I  
 12 gave you an answer to that question.

13 QUESTIONS BY MR. TSAI:

14 Q. Have you ever worked or  
 15 consulted for the FDA?

16 A. No.

17 Q. What is the FDA?

18 A. The FDA is an entity that's  
 19 involved with approving drugs for medical  
 20 use.

21 Q. Do you have any experience  
 22 working on the submission of any NDA to the  
 23 FDA?

24 A. No.

25 Q. Do you have any experience

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1 working on the submission of any ANDA to the  
 2 FDA?

3 A. No.

4 Q. What is an NDA?

5 A. I don't know.

6 Q. What is an ANDA?

7 A. I don't know.

8 Q. Have you ever worked on the

9 submission -- do you have any experience  
 10 working on the submission of any prescription  
 11 medication marketing materials to the FDA for  
 12 government approval?

13 A. I served on the research  
 14 advisory panel of California where we  
 15 reviewed studies that were being conducted in  
 16 the state of California on using various  
 17 investigative pharmaceuticals and my role was  
 18 to assess the safety of those studies. And  
 19 so in that sense I have reviewed numerous  
 20 studies in the process of companies seeking  
 21 FDA approval for their drug.

22 Q. And what was the connection in  
 23 that panel to any company's marketing  
 24 material?

25 A. Well, it wasn't marketing

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1 material, per se.

2 Q. Do you have any experience  
 3 regarding FDA regulations that govern  
 4 pharmaceutical marketing?

5 A. No.

6 Q. Have you ever treated any  
 7 person in Cuyahoga or Summit Counties for  
 8 opioid addiction?

9 A. No.

10 Q. Have you ever treated any  
 11 patients in Cuyahoga or Summit Counties for  
 12 any medical condition related to opioids?

13 A. No.

14 Q. Have you ever been to Summit  
 15 County?

16 A. No, but I have been to Cuyahoga  
 17 County.

18 Q. Are you able to identify any  
 19 particular individuals whose opioid addiction  
 20 or overdose led to costs incurred by Cuyahoga  
 21 or Summit Counties?

22 MR. ARBITBLIT: Object to form.

23 THE WITNESS: I am able to -- I  
 24 have analyzed the CDC data from Ohio,  
 25 including Summit and Cuyahoga

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1 Counties, and so I can speak to the  
 2 issue of the opioid epidemic in those  
 3 counties.

4 QUESTIONS BY MR. TSAI:

5 Q. Is the CDC data that you are  
 6 referring to specific to any particular  
 7 individuals residing in those counties that  
 8 allows you to identify their medical  
 9 condition or the circumstances of their  
 10 opioid use?

11 MR. ARBITBLIT: Object to form.  
 12 THE WITNESS: The CDC data is  
 13 looking at individuals in aggregate,  
 14 not any one individual that I could  
 15 identify.

16 QUESTIONS BY MR. TSAI:

17 Q. Have you ever asked for or been  
 18 provided any information specific to Cuyahoga  
 19 or Summit Counties regarding individual  
 20 persons whose addiction the counties contend  
 21 led to costs in this case?

22 MR. ARBITBLIT: I'll instruct  
 23 you not to answer as to that question  
 24 because it involves the  
 25 attorney-expert privilege.

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1                   Don't answer.

2    QUESTIONS BY MR. TSAI:

3       Q.     Let me rephrase it.

4                   Have you ever reviewed any

5    information specific to Cuyahoga or Summit

6    Counties regarding any actual individuals

7    whose opioid addiction the counties contend

8    led to the costs that they're seeking in this

9    case?

10      A.    Well, I have reviewed

11    information specific to Cuyahoga and Summit

12    Counties regarding individuals living in

13    those counties broadly speaking as an

14    aggregate, not any one individual. I haven't

15    personally treated any one individual living

16    in those counties.

17      Q.    Well, let me ask it this way:

18    Do you have any basis to tell us whether for

19    any individual in Cuyahoga and Summit

20    Counties whose opioid addiction or overdose

21    allegedly led the counties to incur expenses,

22    the clinical context of their opioid use?

23      MR. ARBITBLIT: Object to form.

24      THE WITNESS: Yes, I believe

25      that I do.

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1    QUESTIONS BY MR. TSAI:

2       Q.     How so?

3       A.     Well, the opioid epidemic is an

4    epidemic that has affected every region

5    across the United States. I have deeply

6    studied the factors contributing to the

7    epidemic, and it's very clear that Cuyahoga

8    and Summit Counties are -- have been involved

9    and have been deeply affected and harmed by

10    the opioid epidemic and so the individual

11    harm that has come to people living in those

12    counties is included in the work that I have

13    done more broadly to understand the opioid

14    epidemic.

15      MR. TSAI: I'll respectfully

16    move to strike.

17    QUESTIONS BY MR. TSAI:

18      Q.    I'm asking about particular

19    individuals who experienced opioid addiction

20    or opioid use disorder and reside in Cuyahoga

21    and Summit Counties.

22      Can you identify any single

23    individual and tell us, for example, the

24    severity of their pain?

25      MR. ARBITBLIT: Object to form.

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1       THE WITNESS: I have not

2       treated an individual in Cuyahoga

3       County, but I feel that that does not

4       preclude me from speaking to the

5       problem of opioid addiction and

6       overdose deaths in those counties.

7    QUESTIONS BY MR. TSAI:

8       Q.     Putting aside the fact that you

9       haven't treated any individual in Cuyahoga or

10      Summit Counties, can you -- do you have a

11      basis based upon any -- anything that you've

12      written, any works that you've done, to

13      identify for any actual individual with

14      opioid use disorder residing in those

15      counties the severity of that individual's

16      pain?

17      MR. ARBITBLIT: Object to form.

18      Asked and answered.

19      THE WITNESS: I feel like I've

20      answered this question.

21    QUESTIONS BY MR. TSAI:

22      Q.     Is the answer no?

23      MR. ARBITBLIT: Object to form.

24      THE WITNESS: The answer is

25      yes.

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1    QUESTIONS BY MR. TSAI:

2       Q.     The answer -- okay. Then if

3       the answer is yes, tell me -- give me a

4       specific example of an individual resident in

5       Cuyahoga and Summit County with opioid use

6       disorder and tell me the circumstances and

7       the extent of their pain condition at the

8       time they used opioids?

9      MR. ARBITBLIT: Object to form.

10     THE WITNESS: The circumstances

11     of individuals in Summit and Cuyahoga

12     Counties mirror the circumstances of

13     individuals across the United States

14     vis-à-vis the opioid epidemic. There

15     are patterns that have been replicated

16     that apply to those individuals.

17      I have not personally treated

18      an individual in Cuyahoga or Summit

19      County, but I still believe that I can

20      speak to and have an opinion on the

21      problem of opioid addiction, overdose

22      deaths of individuals in those

23      counties.

24    QUESTIONS BY MR. TSAI:

25      Q.     So to be clear, your assumption

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1 that there are similar circumstances is not  
 2 based on any treatment of any actual  
 3 individual, correct?

4 MR. ARBITBLIT: Object to form.  
 5 Argumentative. Asked and answered.

6 She's answered the question  
 7 five different ways, and you've asked  
 8 it five different ways. It's the same  
 9 question.

10 MR. TSAI: She hasn't answered.  
 11 MR. ARBITBLIT: I disagree.

12 THE WITNESS: Yeah, I think  
 13 I've answered it.

14 QUESTIONS BY MR. TSAI:

15 Q. What is the basis of your  
 16 assumption that any particular case of opioid  
 17 use disorder of a resident of Cuyahoga and  
 18 Summit Counties is, as you say, similar to  
 19 patterns that you refer to?

20 MR. ARBITBLIT: Objection.

21 Argumentative.

22 THE WITNESS: I've treated many  
 23 individuals with opioid use disorders  
 24 over many years. The natural history  
 25 and progression of the disease of

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1 addiction is similar in every  
 2 individual that I have treated.  
 3 I have no basis to believe that  
 4 that would be any different for the  
 5 individuals in Cuyahoga and Summit  
 6 Counties.

7 QUESTIONS BY MR. TSAI:

8 Q. Did you review a single medical  
 9 record related to an individual in Cuyahoga  
 10 and Summit County?

11 MR. ARBITBLIT: Asked and  
 12 answered.

13 She's told you she has not  
 14 reviewed them, Counsel. You keep  
 15 asking the same question.

16 QUESTIONS BY MR. TSAI:

17 Q. So the answer is you have not  
 18 reviewed any medical records related to  
 19 actual individuals in Cuyahoga and Summit  
 20 Counties?

21 A. I have not reviewed any  
 22 individual medical record.

23 Q. So, therefore, you don't have a  
 24 basis to say that any individual with opioid  
 25 use disorder in Cuyahoga and Summit Counties

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1 had a prior or current pattern of substance  
 2 abuse disorder?

3 MR. ARBITBLIT: Objection.

4 Asked and answered. Argumentative.

5 THE WITNESS: I disagree.

6 QUESTIONS BY MR. TSAI:

7 Q. Then what is your basis?

8 MR. ARBITBLIT: Let's move on.  
 9 If you keep asking this question, we  
 10 can always call the discovery master.

11 MR. TSAI: You can feel free --  
 12 we can go off the record --

13 MR. ARBITBLIT: You're going to  
 14 waste your time and keep asking the  
 15 same question. It's your clock.

16 If you have anything else to  
 17 say about it, you can.

18 THE WITNESS: I don't have  
 19 anything else to say.

20 QUESTIONS BY MR. TSAI:

21 Q. What is your basis to  
 22 extrapolate to the conclusion that any  
 23 particular individual with opioid use  
 24 disorder in Cuyahoga and Summit Counties did  
 25 or did not have a co-occurring or preexisting

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1 mental illness or medical condition?

2 MR. ARBITBLIT: Object to form.

3 Asked and answered.

4 THE WITNESS: I don't have  
 5 another answer.

6 QUESTIONS BY MR. TSAI:

7 Q. Are you able to identify any  
 8 particular doctors who prescribed opioid  
 9 medications to individuals in Cuyahoga and  
 10 Summit Counties?

11 A. When you say "identify," do you  
 12 mean you want me to produce specific names?

13 Q. Yes.

14 Are you able to -- that's what  
 15 I mean by identify, yes.

16 A. Okay. No.

17 Q. Did you review any materials  
 18 that would give you a basis for you to  
 19 analyze or opine about what led any doctor to  
 20 prescribe an opioid medication to their  
 21 patients in Cuyahoga and Summit Counties?

22 MR. ARBITBLIT: Object to form.

23 THE WITNESS: Yes.

24 QUESTIONS BY MR. TSAI:

25 Q. Okay. What materials do you

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1 have in mind?

2 A. I have in mind the misleading  
3 messaging that was put forward by the  
4 defendants to persuade doctors to prescribe  
5 opioids for minor and chronic pain conditions  
6 in the absence of evidence to do so.

7 Q. Okay. And is that also on an  
8 aggregate basis?

9 A. Yes.

10 Q. So can you identify a single  
11 doctor in Cuyahoga and Summit Counties who  
12 relied on a particular statement of any  
13 defendant in deciding to treat his or her  
14 patient with prescription opioid medications?

15 MR. ARBITBLIT: Object to form.

16 THE WITNESS: I can identify  
17 such doctors, but not by name because  
18 I don't know their names. They're  
19 individuals that I met when I was  
20 giving talks to educate physicians in  
21 the state of Ohio who reported to me  
22 as part of that teaching that I was  
23 doing that they had prescribed opioids  
24 in ways that they regretted, and that  
25 they did so because of the misleading

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1 messaging put forward by the  
2 pharmaceutical opioid industry.

3 QUESTIONS BY MR. TSAI:

4 Q. Okay. And when you say "giving  
5 talks to educate physicians in Ohio," what  
6 are you referring to?

7 A. I'm going to look at my report.

8 Q. And I believe we've premarked  
9 your report as Exhibit 1.

10 A. So in April of 2018, I was the  
11 keynote speaker at Star Trauma Recovery  
12 Center at Ohio State University Medical  
13 School in Columbus, Ohio, where I spoke on  
14 the opioid epidemic.

15 Also in February 2019, I was  
16 the keynote speaker at an Ohio State  
17 University interprofessional summit in  
18 Columbus, Ohio, where I spoke on the issue of  
19 the opioid epidemic.

20 Q. And the conversations that you  
21 referred to with doctors in connection with  
22 these speeches, did you memorialize them in  
23 any way?

24 A. What do you mean by  
25 "memorialize"?

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1 Q. Do you have any written records  
2 of them?

3 A. No.

4 Q. Staying with your report, you  
5 have a term called the "Tsunami Effect,"  
6 capital T, capital E. And this is on page 88  
7 of your report.

8 Is the Tsunami Effect a  
9 description of an outcome, or is it a causal  
10 model with predictive power?

11 MR. ARBITBLIT: Object to form.  
12 Compound.

13 THE WITNESS: The Tsunami  
14 Effect is a way of describing the  
15 impact of flooding our society with  
16 huge numbers of opioid pills leading  
17 to the harm of individuals, not just  
18 because they themselves had received  
19 an opioid prescription, but because  
20 they then had access to opioids  
21 through somebody else's prescription.

22 So kind of a flooding metaphor.  
23 An example would be for a teenager who  
24 decides to take his or her  
25 grandmother's pills in experimentation

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1 and is subsequently harmed as a result  
2 of taking those pills.

3 QUESTIONS BY MR. TSAI:

4 Q. So in that example, the  
5 teenager is a person who has not been  
6 prescribed that particular opioid medication,  
7 correct?

8 A. In that particular example,  
9 yes.

10 MR. ARBITBLIT: Wait for the  
11 question before you answer.

12 QUESTIONS BY MR. TSAI:

13 Q. And in that example, the  
14 teenager has not been evaluated or advised by  
15 a physician, correct?

16 A. In that example, that's  
17 correct.

18 Q. Does the Tsunami Effect predict  
19 what individuals in particular cities and  
20 counties will become addicted to or overdose  
21 from opioids?

22 A. I would like to refer to my  
23 report for a moment.

24 Q. Do you have that?  
25 (Lembke Exhibit 1 marked for

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1 identification.)

2 QUESTIONS BY MR. TSAI:

3 Q. Let's go ahead and mark the  
4 report as Exhibit 1.

5 A. Sorry, I'm looking for that  
6 particular article that I reviewed.

7 Can you repeat the question?

8 Q. Sure.

9 Let me say -- ask you this in a  
10 different way, but let me back up.

11 Have you ever published the  
12 Tsunami Effect theory in any peer-reviewed,  
13 scientific journal?

14 A. Well, my book was published by  
15 Johns Hopkins University Press, and it went  
16 through a peer-review process. And although  
17 I don't believe that I used the term "the  
18 Tsunami Effect" in my book, I do discuss the  
19 more general principle of the problem of  
20 increased access to opioid medication being  
21 the major cause of this epidemic, not just  
22 for individuals directly prescribed the  
23 opioid, but for all those individuals who  
24 have increased access as a result of that  
25 prescription.

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1 Q. Your book, "Drug Dealer, MD,"  
2 is not a peer-reviewed, scientific journal,  
3 correct?

4 MR. ARBITBLIT: Object to form.  
5 THE WITNESS: My book was  
6 published by an academic press, a very  
7 esteemed one, Johns Hopkins University  
8 Press, and it went through a  
9 peer-review process prior to  
10 publication, and in that sense stands  
11 out as distinct from, for example, a  
12 trade book.

13 QUESTIONS BY MR. TSAI:

14 Q. Is it your statement that the  
15 peer-review process for publication of your  
16 book is the same as a peer-review process to  
17 get an article published in a scientific  
18 journal?

19 A. Yes.

20 Q. Other than your book, have you  
21 published in any peer-reviewed, scientific  
22 journal regarding the Tsunami Effect?

23 A. No.

24 Q. Have you ever tested the  
25 Tsunami Effect theory to quantify what

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1 persons ultimately addicted to opioids were  
2 individuals whose initial exposure was via a  
3 medically appropriate prescription of an  
4 opioid medication for a legitimate pain  
5 condition?

6 MR. ARBITBLIT: Object to form.

7 THE WITNESS: I have not done  
8 the research to quantify that. I have  
9 done the research, the qualitative  
10 research, on that.

11 And further, I would say that  
12 others have done research showing that  
13 there's a very intimate link between  
14 the nonmedical use of opioid pain  
15 pills and the subsequent development  
16 of addiction and the medical use of  
17 opioid pain pills.

18 So those are all intertwined,  
19 and I think that has been established  
20 in the literature, and it's also in my  
21 report.

22 QUESTIONS BY MR. TSAI:

23 Q. And an example of a nonmedical  
24 use of opioid pain medications is using an  
25 opioid, knowing that you're not the person

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1 who was prescribed the medication; is that  
2 correct?

3 A. No.

4 Q. Oh, is an example of a  
5 nonmedical use of opioid pain pills to  
6 deliberately get a high as opposed to treat  
7 the pain condition?

8 A. No, not exclusively.

9 Q. Is that one example of a  
10 nonmedical use of opioids as you've referred  
11 to it?

12 A. That is one example.

13 Q. Does the Tsunami Effect include  
14 within its scope individuals who deliberately  
15 misused a prescription opioid medication  
16 knowing that the medication was not  
17 prescribed to them?

18 A. Yes.

19 Q. Does the Tsunami Effect include  
20 within its scope individuals who deliberately  
21 misused a prescription opioid medication  
22 knowing they were using it in violation of  
23 the medication's warning label?

24 For example, crushing a pill in  
25 order to snort the powder they made to get a

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1 high?  
 2 MR. ARBITBLIT: Object to form.  
 3 THE WITNESS: I very much doubt  
 4 that the warning label came into  
 5 consideration in that context when  
 6 you're dealing with a teenager who is  
 7 experimenting, who has access to that  
 8 pill because it was prescribed to a  
 9 relative and so readily available.

10 QUESTIONS BY MR. TSAI:

11 Q. So just to be clear,  
 12 individuals who deliberately misuse an  
 13 opioid, for example, crushing it, snorting  
 14 it, injecting, in order to get a high, those  
 15 are included in your Tsunami Effect?

16 A. Yes.

17 Q. Have you ever tested the  
 18 Tsunami Effect to rule out the inclusion of  
 19 individuals who deliberately committed a  
 20 crime in obtaining and using opioids?

21 MR. ARBITBLIT: Object to form.

22 THE WITNESS: The Tsunami  
 23 Effect isn't really about whether or  
 24 not that individual committed a crime.

25 The Tsunami Effect is really

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1 trying to capture the very real  
 2 phenomenon of flooding in our society  
 3 of opioid medication as a result of  
 4 misleading messaging by the defendants  
 5 that led to the use of those opioids  
 6 in minor and chronic pain conditions  
 7 and then made them readily accessible,  
 8 not just to people who were prescribed  
 9 opioids, but even those not being  
 10 prescribed opioids.

11 QUESTIONS BY MR. TSAI:

12 Q. And to be clear about the scope  
 13 of this phenomenon, as you call it, does the  
 14 Tsunami Effect include within its scope  
 15 individuals who deliberately committed a  
 16 crime in obtaining and using opioids?

17 MR. ARBITBLIT: Object to form.

18 THE WITNESS: Yes.

19 QUESTIONS BY MR. TSAI:

20 Q. And just in going back to our  
 21 discussion about your practice of prescribing  
 22 opioid medications to your patients, can you  
 23 name the opioid medications that you have  
 24 prescribed over the course of your career?

25 A. I have prescribed opioids,

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1 Schedule II opioids, over the course of my  
 2 career, probably every one that you could  
 3 imagine in the course of inpatient treatment.  
 4 And I can't specifically name  
 5 them because I can't recollect the specific  
 6 instances.

7 In recent years, especially  
 8 practicing as an outpatient provider, I  
 9 primarily prescribe buprenorphine-naloxone in  
 10 the use of opioid use disorder.

11 Q. Have you prescribed oxycodone?

12 A. Not to my recollection in  
 13 certain years. There may have been instances  
 14 when I temporarily took over that  
 15 prescription in the case of a patient that I  
 16 inherited in an effort to help them taper off  
 17 of that medication, but normally I would not  
 18 do that.

19 Normally I would collaborate  
 20 with my pain colleague and advise them how to  
 21 help that patient taper down to a safer dose  
 22 or come off the medication, oxycodone, all  
 23 together.

24 Q. And when you refer to a pain  
 25 colleague that you would collaborate with,

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1 what are you referring to?  
 2 A. Well, I have a courtesy  
 3 appointment at Stanford University School of  
 4 Medicine in the department of pain. Those  
 5 courtesy appointments are given out in  
 6 recognition of my expertise in the treatment  
 7 of pain. I see patients within the Stanford  
 8 University School of Medicine Pain Clinic.  
 9 In that context, I regularly collaborate with  
 10 my pain colleagues around complex patients.  
 11 We have interdisciplinary team treatment  
 12 meetings where we will discuss those patients  
 13 in collaboration to try to come together to  
 14 find the best treatment plan.

15 I also frequently communicate  
 16 with my pain colleagues using the electronic  
 17 medical records system and by telephone as we  
 18 collaborate together to come up with the best  
 19 treatment plan for our patients with pain.

20 Q. Are there any particular  
 21 branded opioid medications that you can  
 22 recall prescribing?

23 A. No.

24 Q. Do you recall prescribing  
 25 hydromorphone?

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1 A. I think I already answered that  
2 question.

3 Q. What was your answer? I don't  
4 recall.

5 A. I don't recall any specific  
6 pain medications that I prescribed outside of  
7 the buprenorphine-naloxone that I now  
8 prescribe regularly in my outpatient  
9 practice.

10 Q. Do you have any experience or  
11 expertise in regard to the prescription drug  
12 supply chain?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: I am aware of the  
15 role of the distributors in this case.  
16 I have read the complaint. I do  
17 acknowledge their contribution to the  
18 opioid epidemic, in particular the  
19 flooding of pills in small towns that  
20 should have alerted them to a problem,  
21 which they did not take action on.

22 MR. TSAI: Respectfully move to  
23 strike that answer.

24 QUESTIONS BY MR. TSAI:

25 Q. Have you ever worked for a

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1 pharmaceutical company or consulted for one?

2 A. No.

3 Q. Do you have any experience or  
4 expertise regarding the setting of DEA quotas  
5 for prescription opioid medications?

6 A. I'm aware of DEA quotas. I'm  
7 aware of the discussion around them vis-à-vis  
8 the opioid epidemic.

9 Q. Do you agree that the  
10 defendants in this case are part of the legal  
11 prescription medicine manufacturing and  
12 supply business?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: I guess I'm  
15 not -- I don't really understand the  
16 question.

17 QUESTIONS BY MR. TSAI:

18 Q. The defendants in this case are  
19 making and selling legally approved,  
20 government-regulated medicines?

21 MR. ARBITBLIT: Is that a  
22 question or a statement?

23 QUESTIONS BY MR. TSAI:

24 Q. Do you agree?

25 A. Is that a question or a

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1 statement?

2 Q. I said, do you agree with that?

3 A. Could you rephrase the  
4 question?

5 Q. The defendants in the case are  
6 making and selling legally approved,  
7 government-regulated medicines; is that  
8 correct?

9 A. Well, I guess I would object to  
10 the form of the question, especially the  
11 government-regulated medicine part. I think  
12 that the defendants in this case have also  
13 had a major responsibility in that process of  
14 regulation.

15 Q. Do you have any basis to say  
16 that defendants are selling medicines that  
17 are not legally approved?

18 MR. ARBITBLIT: Object to form.

19 THE WITNESS: Yes, the  
20 medicines are legally approved.

21 QUESTIONS BY MR. TSAI:

22 Q. Do you agree that there are  
23 multiple steps between a prescription opioid  
24 medication being approved by the government  
25 on the one hand and the effects, the

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1 phenomenon that you call the Tsunami Effect?

2 MR. ARBITBLIT: Object to form.  
3 THE WITNESS: I guess I would  
4 want to know what multiple steps  
5 you're referring to.

6 QUESTIONS BY MR. TSAI:

7 Q. Well, as you envisioned the  
8 Tsunami Effect, do you agree that for any of  
9 the prescription opioid medications that you  
10 refer to in your report -- first, it has to  
11 be submitted for FDA approval?

12 A. Yes.

13 Q. And are you familiar with what  
14 requirements must be met in order for the  
15 government to approve a prescription opioid  
16 medication as safe and effective?

17 A. I am familiar, but I have not  
18 been asked to opine on that aspect of the  
19 case.

20 Q. And in addition to approval by  
21 the Food and Drug Administration as safe and  
22 effective, do you agree that opioid  
23 medications must be approved by the DEA for  
24 manufacturing and sale?

25 A. Yes.

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1 Q. Okay. And then once an opioid  
 2 medication pill is made, what is your  
 3 understanding of how it makes its way to an  
 4 actual individual in Cuyahoga and Summit  
 5 Counties for use?

6 MR. ARBITBLIT: Object to form.

7 THE WITNESS: Well, there's the  
 8 production part, and then there's the  
 9 distribution part where it's then  
 10 transported to a pharmacy, and then  
 11 the pharmacy is the dispensing agent  
 12 for that pill.

13 QUESTIONS BY MR. TSAI:

14 Q. And before any individual in  
 15 Cuyahoga and Summit Counties can obtain an  
 16 opioid, they need to get a prescription from  
 17 a doctor, correct?

18 MR. ARBITBLIT: Object to form.

19 THE WITNESS: Yes.

20 QUESTIONS BY MR. TSAI:

21 Q. Okay. So if we could discuss  
 22 one of the articles that you cite in your  
 23 study.

24 MR. TSAI: Can we have Tab 3,  
 25 the McCabe study?

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1 QUESTIONS BY MR. TSAI:

2 Q. And, Dr. Lembke, you cited this  
 3 on page 40 of your report.  
 4 Are you familiar -- do you  
 5 recall citing the McCabe prospective study?  
 6 (Lembke Exhibit 2 marked for  
 7 identification.)

8 MR. ARBITBLIT: Is this  
 9 Exhibit 2?

10 MR. TSAI: Yes, the exhibit  
 11 next in order, Exhibit 2.

12 MR. ARBITBLIT: Thank you.

13 THE WITNESS: Are you sure it's  
 14 page 40? I think it's 39.

15 QUESTIONS BY MR. TSAI:

16 Q. So the McCabe study uses the  
 17 term "NMUPO."

18 Do you recall that?

19 A. Yes.

20 Q. And what does the term "NMUPO"  
 21 mean?

22 A. Nonmedical use of prescription  
 23 opioids.

24 Q. So one example of NMUPO would  
 25 mean that the individual who is taking and

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1 ingesting the opioid was not the person who  
 2 was supposed to use the prescription  
 3 medicine; do you agree?

4 A. That's -- that is how they  
 5 defined it in this paper, yes.

6 Q. So an example is a teenager  
 7 goes into a friend of a friend's house or a  
 8 neighbor's house and takes leftover  
 9 prescription opioid pills that have been  
 10 prescribed to that friend of a friend or  
 11 neighbor but not to the teenager, correct?

12 A. Yes.

13 Q. Another example of NMUPO is  
 14 that the individual who was supposed to  
 15 receive the prescription for the opioid  
 16 medication misused it for a nonmedical  
 17 purpose to get high instead of to treat a  
 18 legitimate pain condition, correct?

19 A. Can I see the article?

20 Q. It's --

21 A. So I'm seeing their definition  
 22 of nonmedical use of prescription opioids as,  
 23 quote, "taking any narcotics other than  
 24 heroin on your own, that is, without a doctor  
 25 telling you to take them."

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1 Q. And in your understanding of a  
 2 misuse of an opioid medication, does that  
 3 include taking an opioid medication for  
 4 longer periods or in higher doses or  
 5 different doses than the doctor instructed  
 6 you to?

7 A. Yes.

8 Q. So if you could turn to  
 9 page 379 of Exhibit 2, the McCabe article,  
 10 and if you could look at the right-hand  
 11 column, you see the Section 3, results?

12 A. Uh-huh.

13 Q. And if you could look at the  
 14 second paragraph, it says, "Among adolescents  
 15 who engaged in past-year NMUPO, approximately  
 16 95 percent also used other substances and the  
 17 majority simultaneously co-ingested  
 18 prescription opioids with other substances,  
 19 55.2 percent."

20 Do you see that?

21 A. Yes, I do.

22 Q. What is your understanding of  
 23 what "other substances" means?

24 A. Substances in the medical  
 25 literature typically refers to any potential

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1       addictive substance.

2           Q.     So looking at that finding and  
3     the 95 percent number, am I correct that  
4     means that virtually all of the individuals  
5     who were found to be nonmedical prescription  
6     opioid users were also using other addictive  
7     substances, things like alcohol and  
8     marijuana?

9           A.     Yes, that's what this sentence  
10   means.

11          Q.     And it's not surprising that  
12   folks who used lots of different drugs when  
13   they were teenagers had drug problems,  
14   including opioid addiction, alcohol addiction  
15   and marijuana addiction, when they were  
16   adults; do you agree?

17           MR. ARBITBLIT: Object to form.

18          THE WITNESS: So 90 percent of  
19   adolescents who use some sort of  
20   addictive substances -- substance  
21   during their teenager years do not go  
22   on to become persons with addiction.  
23   It's about 10 to 15 percent of those  
24   individuals will develop a substance  
25   use disorder.

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1           My point being that adolescence  
2     is a time of experimentation where  
3     many young people will try a variety  
4     of substances. So it's not  
5     particularly surprising that these  
6     individuals have experimented with  
7     whatever substances were readily  
8     available to them. As another aspect  
9     of adolescent addiction, that  
10   adolescents have more barriers, cost  
11   barriers, transportation barriers,  
12   than adults who use substances, and so  
13   they will typically use substances  
14   that are readily available to them.

15           So this is not a surprise to  
16   me. This is what I'm trying to say.

17          QUESTIONS BY MR. TSAI:

18          Q.     And if you turn to page 381,  
19   progressing and tracking how these teenagers,  
20   who, as you were saying, are experimenting  
21   with things that are available like alcohol  
22   and marijuana, if you look at 381 and you see  
23   3.2?

24          A.     Yes, I do.

25          Q.     And the second paragraph, I'll

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1       read the first sentence. It says, "We found  
2   that adolescents who engaged in simultaneous  
3   co-ingestion of NMUPO and other drugs had  
4   significantly greater odds of AUD, CUD, ODUD  
5   and any SUD symptoms at age 35 relative to  
6   those with had no history of NMUPO during  
7   adolescence."

8           Do you see that?

9          A.     Yes, I do.

10        Q.     Okay. And AUD stands for  
11   alcohol use disorder?

12        A.     That's correct.

13        Q.     CUD stands for cannabis use  
14   disorder?

15        A.     Yes.

16        Q.     And that's marijuana addiction?

17        A.     That's correct.

18        Q.     ODUD stands for what?

19        A.     Other drug use disorder.

20        Q.     And SUD stands for what?

21        A.     Substance use disorder.

22        Q.     And substance use disorder  
23   would be the aggregate and all-encompassing  
24   category of addictive substances?

25        A.     That's right.

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1           Q.     So is it -- it's not surprising  
2   that folks who use prescription opioids --  
3   well, strike that.

4           Then if you can go down to the  
5   one, two, three, four -- fifth paragraph of  
6   3.2, the authors state another finding, and  
7   I'll read it, the first sentence.

8        "Adolescents who indicated medical use  
9   without a history of NMUPO did not differ  
10   from adolescents with no history of medical  
11   use of prescription opioids or NMUPO in the  
12   odds of AUD, CUD, ODUD and any SUD symptoms."

13        Do you see that?

14        A.     Yes, I do.

15        Q.     And when they say "medical  
16   use," am I right to read that as the opposite  
17   of NMUPO?

18        Medical use is the opposite of  
19   nonmedical use of prescription opioids?

20        A.     That's fair.

21        Q.     So am I reading this finding  
22   correctly that it's not surprising that folks  
23   who use prescription opioids following  
24   doctor's orders and as they were supposed to  
25   when teenagers did not tend to have drug

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1 problems when they were adults?

2 A. I wouldn't interpret it that

3 way, necessarily, no.

4 Q. Well, doesn't it say that

5 adolescents with medical use of prescription

6 opioids who had no history of nonmedical use

7 were as unlikely to have opioid addiction

8 problems as folks who had never used

9 prescription opioids at all when they were

10 younger?

11 MR. ARBITBLIT: Object to form.

12 THE WITNESS: This statement

13 doesn't necessarily mean that those

14 who are exposed to an opioid medically

15 are not at risk for developing

16 addiction. There's good evidence to

17 show that even individuals exposed to

18 an opioid medically are at increased

19 risk for developing an opioid use

20 disorder, specifically an article

21 which I cite in my report on page 40

22 by Schroeder, et al., shows that even

23 very limited exposure in persons age

24 16 to 25 years old who received an

25 initial opioid prescription from a

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1 dentist, approximately 6 percent of

2 them were later diagnosed with an

3 opioid use disorder within a year.

4 My point being that there is a

5 risk with exposure to medical use of

6 opioids, not just to nonmedical use of

7 opioids.

8 MR. ARBITBLIT: And Federal

9 Rule 106, Rule of Completeness,

10 Counsel, page 378 of the article

11 you're reading from states exactly

12 this, "Medical use of prescription

13 opioids during adolescence is

14 associated with greater odds of

15 subsequent prescription opioid

16 misuse," citing Harbaugh 2018, McCabe,

17 2013, and '16, and Mlech, 2015.

18 MR. TSAI: I object to

19 counsel's testimony.

20 MR. ARBITBLIT: It's not

21 testimony. It's the Rule of

22 Completeness, Counsel. You should be

23 familiar with it.

24 MR. TSAI: The --

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1 QUESTIONS BY MR. TSAI:

2 Q. So putting aside absolute risk,

3 and we'll talk about risk later on, but what

4 is your -- this is a finding comparing

5 likelihood of addictive substance use

6 disorder in two groups, correct, adolescents

7 who had medical use of prescription opioids,

8 no history of nonmedical use or abuse, and

9 adolescents who never took prescription

10 opioids, correct?

11 Am I reading that correct?

12 MR. ARBITBLIT: Object to form.

13 THE WITNESS: So to me, this --

14 that statement that you just read is

15 good evidence for the Tsunami Effect.

16 That basically because there has been

17 increased access to opioids, including

18 for teenagers, that has subsequently

19 increased their risk of going on to

20 develop some kind of substance use

21 problem.

22 MR. TSAI: I move to strike.

23 QUESTIONS BY MR. TSAI:

24 Q. What is your -- what is the --

25 the meaning of the finding that adolescents

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1 who indicated medical use without a history

2 of NMUPO did not differ from adolescents when

3 no history of medical use of prescription

4 opioids or NMUPO in the odds of substance use

5 disorders?

6 Can you tell the jury what that

7 means, in your opinion?

8 A. That means comparing the risk

9 in those two populations, they had similar

10 risk.

11 Q. So I wanted to ask you --

12 turning back to Exhibit 1, which is your

13 report, on page 89, you talk about

14 hepatitis C, HIV and other infectious

15 diseases.

16 Have you reviewed any data to

17 reliably rule out the likelihood that cases

18 of hepatitis C, HIV or other infectious

19 diseases were caused by actions independent

20 from opioid use?

21 A. No.

22 Q. And actions independent of

23 opioid use that are associated or that cause

24 infectious diseases like HIV and hepatitis C

25 include risky sexual conduct, for example; do

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1 you agree?

2 A. Yes.

3 Q. Have you reviewed any data to  
4 reliably rule out the likelihood that cases  
5 of hepatitis C, HIV or other infectious  
6 diseases you refer to existed prior to any  
7 opioid addiction or opioid abuse?

8 A. No.

9 Q. Do you have any -- did you  
10 conduct any analysis, or do you have any  
11 basis to quantify what percentage of cases of  
12 hepatitis C, HIV and other infectious  
13 diseases that you refer to were caused by  
14 reasons that had nothing to do with opioid  
15 use?

16 A. No.

17 Q. And just to be clear, opioid  
18 use disorder and addiction are not  
19 contagious, infectious diseases, correct?

20 A. I would sort of disagree with  
21 that.

22 Q. Is there a pathogen? Is there  
23 an opioid use pathogen?

24 MR. ARBITBLIT: Let her finish  
25 her answer.

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1 THE WITNESS: There is not a  
2 pathogen, per se, but the way that  
3 opioid use disorder has spread through  
4 the population is quite similar in  
5 pattern to the way that infectious  
6 diseases spread through close  
7 contacts.

8 QUESTIONS BY MR. TSAI:

9 Q. If I touch someone who has  
10 opioid use disorder, do I get opioid use  
11 disorder?

12 A. No, but you also don't get HIV.

13 Q. If I receive a blood  
14 transfusion from someone with opioid use  
15 disorder, do I get opioid use disorder?

16 A. No.

17 MR. ARBITBLIT: Counsel, we've  
18 been going just over an hour.  
19 Is it time for a little break?

20 MR. TSAI: Sure. Off the  
21 record, please.

22 VIDEOGRAPHER: We're going off  
23 the record, and the time is 9:11 a.m.  
24 (Off the record at 9:11 a.m.)

25 VIDEOGRAPHER: We are now going

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1 back on the record, and the time is  
2 9:23 a.m.

3 QUESTIONS BY MR. TSAI:

4 Q. And just one quick note: In  
5 most depositions, we don't have this handy  
6 LiveNote screen, and I've noticed that you've  
7 been hearing my questions but also reading.  
8 If I could ask you just to  
9 listen to my questions. If you need  
10 clarification, you can certainly look, but  
11 this does -- if you kind of double up, it  
12 does take up more time.

13 MR. ARBITBLIT: I'll instruct  
14 you to pay no attention to that. You  
15 look at the screen. The questions are  
16 complex. It's serious litigation.  
17 Do what you need to do to  
18 understand the question.

19 QUESTIONS BY MR. TSAI:

20 Q. So --

21 MR. ARBITBLIT: That's why the  
22 screen's here.

23 QUESTIONS BY MR. TSAI:

24 Q. -- let me turn to the second  
25 capitalized term in your report, "Dependence"

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1 Effect," capital D, capital E, and there you  
2 refer to individuals who become dependent on  
3 opioids independent of addiction.  
4 That's how you defined  
5 Dependence Effect.  
6 What is opioid dependence, in  
7 your words, independent of addiction? What  
8 does that mean?

9 A. So that distinction has become  
10 important with the new criteria for  
11 diagnosing a substance use disorder with the  
12 DSM-V, which -- the DSM-V was a departure  
13 from the DSM-IV in the sense that prior to  
14 the DSM-V, the criteria of physiologic  
15 tolerance and withdrawal counted toward a  
16 diagnosis of addiction.  
17 But with the evolution to the  
18 DSM-V, that no longer counted under the  
19 specific circumstances of a patient receiving  
20 an opioid from a medical doctor and  
21 developing tolerance and withdrawal as a  
22 result of taking that medication, that  
23 opioid, under a prescription as prescribed,  
24 which de facto made it more difficult,  
25 created a higher threshold, essentially, for

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1 diagnosing addiction with the DSM-V, but was  
 2 a way of recognizing that the physiologic  
 3 adaptation to opioids occurs to patients  
 4 taking opioids with a medical -- with a  
 5 medical prescription.

6 And so the DSM-V was an attempt  
 7 to distinguish between those individuals who  
 8 developed physiologic dependence under the  
 9 care of a doctor versus those individuals who  
 10 developed physiologic dependence, probably  
 11 also in many instances under the care of a  
 12 doctor, but also had these other behavioral  
 13 components that we use to signify the problem  
 14 of addiction.

15 Does that answer your question?

16 Q. So do you agree with the  
 17 changes that were implemented in DSM-V's  
 18 diagnostic criteria for opioid use disorder?

19 A. I accept those changes. I  
 20 think that those -- that the physiologic  
 21 dependence, so the neurobiological changes  
 22 that occur in the brain as a result of  
 23 physical dependence on the opioid, can't be  
 24 distinguished necessarily from the  
 25 neurobiological changes that happen in the

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1 brain as a result of this concept of  
 2 addiction, ala DSM-V criteria. But I  
 3 appreciate that a distinct social construct  
 4 was necessary to subclassify those  
 5 individuals who developed physiological  
 6 dependence under the care of a doctor.

7 I actually don't agree with the  
 8 DSM-V criteria in the sense that it raised  
 9 the bar for physicians to be able to diagnose  
 10 the problem of opioid addiction. It's that  
 11 much harder to do.

12 And that, along with the  
 13 pseudoaddiction representation that was put  
 14 forward by the defendants, has essentially  
 15 made it nearly impossible to diagnose opioid  
 16 use disorder addiction in the population of  
 17 patients who become addicted through a  
 18 doctor's prescription, which is a sizeable  
 19 population.

20 Q. So under the prior definition  
 21 of opioid use disorder, under DSM-IV, it was  
 22 easier to diagnose and classify individuals  
 23 as opioid addicts; is that right?

24 MR. ARBITBLIT: Object to form.  
 25 THE WITNESS: Well, we don't

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1 like to use the term "addicts,"  
 2 because it's pejorative.

3 I would say, yes, it has become  
 4 more difficult to diagnose opioid use  
 5 disorder with the DSM-V nomenclature  
 6 for those individuals who become  
 7 addicted to opioids through a doctor's  
 8 prescription.

9 QUESTIONS BY MR. TSAI:

10 Q. So put simply: More people  
 11 would be considered a person with opioid use  
 12 disorder under the prior definition than  
 13 under the updated definition?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: I believe so,  
 16 yes.

17 QUESTIONS BY MR. TSAI:

18 Q. So an example is: I have  
 19 kidney stones, I'm prescribed opioid  
 20 medications by my doctor. I say "I need more  
 21 than the originally prescribed dose to  
 22 relieve my pain." I complete my course under  
 23 the supervision of the doctor, and when I go  
 24 off, I experience withdrawal symptoms.

25 Under the prior framework,

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1 DSM-IV, would I be classified as having  
 2 opioid use disorder?

3 MR. ARBITBLIT: Object to form.  
 4 Incomplete hypothetical.

5 THE WITNESS: It's hard for me  
 6 to make that determination based on  
 7 the limited example that you gave, but  
 8 according to DSM-IV criteria, if you  
 9 had both physical tolerance and  
 10 withdrawal, then that met a low  
 11 threshold criteria for having an  
 12 opioid dependence problem.

13 QUESTIONS BY MR. TSAI:

14 Q. And you agree that tolerance  
 15 and withdrawal are common among all users of  
 16 prescription medications, not just opioid  
 17 medications?

18 MR. ARBITBLIT: Object to form.

19 THE WITNESS: I disagree with  
 20 that. I think that opioids stand  
 21 apart in terms of the degree to which  
 22 there's tolerance, so I think  
 23 tolerance is more common with opioids.

24 I think the dependence syndrome  
 25 is more severe. The withdrawal is

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1 more excruciating for many  
 2 individuals.

3 So I think opioids are distinct  
 4 in that regard.

## 5 QUESTIONS BY MR. TSAI:

6 Q. Well, putting aside qualitative  
 7 degrees or extent or severity, the phenomenon  
 8 of tolerance, the phenomenon of withdrawal,  
 9 you do see that, for example, in  
 10 antidepressants like Paxil; is that right?

11 MR. ARBITBLIT: Object to form.

12 THE WITNESS: The phenomenon of  
 13 tolerance and withdrawal is seen in  
 14 other addictive scheduled drugs. It's  
 15 not as severe as in the case of  
 16 opioids.

17 I would disagree that that  
 18 exact same phenomenon occurs with  
 19 antidepressants. There is something  
 20 called a discontinuation syndrome.  
 21 I've seen it rarely in my career. And  
 22 it's certainly not nearly as  
 23 debilitating as the opioid withdraw --  
 24 as what we see with opioid withdraw.  
 25 Not even in the same universe.

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## 1 QUESTIONS BY MR. TSAI:

2 Q. And discontinuation phenomenon,  
 3 that is, when a person using an  
 4 antidepressant is going off of it, is  
 5 tapering off or down?

6 A. That's right.

7 Q. And they experience withdrawal?  
 8 MR. ARBITBLIT: Object to form.  
 9 THE WITNESS: They experience  
 10 some physical symptoms associated with  
 11 that taper process.

## 12 QUESTIONS BY MR. TSAI:

13 Q. So am I right that  
 14 individuals -- some individuals classified as  
 15 having an opioid use disorder under the prior  
 16 DSM-IV framework would not be deemed to have  
 17 an opioid use disorder under the current  
 18 updated definition?

19 A. That's correct.

20 Q. Okay. And so in tying your  
 21 Dependence Effect phenomenon to dependence as  
 22 opposed to addiction, that's a broader net;  
 23 am I right?

24 A. Yes.

25 Q. It's more permissive?

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1 MR. ARBITBLIT: Object to form.  
 2 THE WITNESS: What do you mean  
 3 by "permissive"?

## 4 QUESTIONS BY MR. TSAI:

5 Q. Well, you said lower bar, upper  
 6 bar.

7 So let me get -- it's a lower  
 8 bar to be considered dependent in your view  
 9 as opposed to addicted?

10 A. I would say the criteria are  
 11 different. I don't think I would use lower  
 12 bar versus higher bar. They're now  
 13 categorized as distinct and separate  
 14 phenomenon.

15 The point of describing the  
 16 Dependence Effect is to communicate that  
 17 there are more than 10 million people in this  
 18 country who have taken opioids as prescribed  
 19 and become physically dependent and that  
 20 that's a very serious and morbid physical  
 21 condition, that being dependent on opioids is  
 22 not some kind of benign or easily reversible  
 23 phenomenon.

24 Q. Does prescribing or dispensing  
 25 of opioid medications always lead to

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1 dependence?  
 2 MR. ARBITBLIT: Object to form.  
 3 THE WITNESS: Almost always,  
 4 yes.

## 5 QUESTIONS BY MR. TSAI:

6 Q. Does it inevitably lead to  
 7 dependence?

8 A. In the vast majority of cases,  
 9 yes.

10 Q. Does it immediately and  
 11 automatically lead to dependence?

12 MR. ARBITBLIT: Object to form.  
 13 THE WITNESS: Not immediately.

14 It takes people varying degrees of  
 15 time. Some people become dependent  
 16 within a matter of days to weeks.

17 Other people can go much  
 18 longer, but in the vast majority of  
 19 cases, people who take opioids daily  
 20 for an extended period of time become  
 21 physically dependent on those opioids,  
 22 such that they need more and more to  
 23 get the same effect. And when they  
 24 reduce their dose or stop taking them  
 25 for some reason, they experience

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1 withdrawal.  
 2 And in many cases the  
 3 withdrawal is excruciating and very  
 4 debilitating.

## 5 QUESTIONS BY MR. TSAI:

6 Q. Have you reviewed any  
 7 information or conducted any analysis to  
 8 quantify what individuals in the counties,  
 9 Cuyahoga and Summit Counties, became opioid  
 10 dependent?

11 MR. ARBITBLIT: Object to form.

12 THE WITNESS: Is this getting  
 13 back to what we talked about before,  
 14 this question?

## 15 QUESTIONS BY MR. TSAI:

16 Q. I don't think I asked about  
 17 opioid dependence.

18 A. Okay. Can you say the question  
 19 again?

20 Q. Have you reviewed any  
 21 information or conducted any analysis to  
 22 quantify what individuals in the counties,  
 23 Cuyahoga and Summit Counties, became opioid  
 24 dependent?

25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: No. No.

2 QUESTIONS BY MR. TSAI:

3 Q. Can the Dependence Effect  
 4 phenomenon predict what individuals in what  
 5 particular cities or counties will become  
 6 addicted to or overdose from opioids?

7 A. Yes.

8 Q. How so?

9 A. People who are dependent on  
 10 opioids are at increased risk to suffer from  
 11 overdose from those opioids, even separate  
 12 from being diagnosed from opioids, and I can  
 13 explain that physiology, if you would like.

14 It's also true that people who  
 15 are opioid dependent are at very high risk to  
 16 go on to meet DSM-V criteria for opioid  
 17 addiction.

18 Q. Well, let me ask it from this  
 19 angle.

20 Have you ever tested the  
 21 Dependence Effect phenomenon to, for example,  
 22 rule out the inclusion of individuals who  
 23 deliberately committed a crime in obtaining  
 24 and using opioids?

25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: I don't  
 2 understand your question.

## 3 QUESTIONS BY MR. TSAI:

4 Q. Have you ever tested the  
 5 Dependence Effect phenomenon -- well, let me  
 6 ask it this way.

7 Does the Dependence Effect  
 8 include within its scope individuals who  
 9 deliberately committed a crime in obtaining  
 10 and using opioids?

11 MR. ARBITBLIT: Object to form.

12 THE WITNESS: Yes.

## 13 QUESTIONS BY MR. TSAI:

14 Q. Does the Dependence Effect  
 15 include within its scope individuals who  
 16 deliberately misused a prescription opioid  
 17 medication knowing that medication was not  
 18 prescribed to him or her?

19 A. The Dependence Effect would  
 20 include anybody who has become  
 21 physiologically dependent on opioids.

22 Q. And that would include  
 23 individuals residing in Cuyahoga and Summit  
 24 Counties whose exposure to opioids was via  
 25 opioids that were not prescribed to them?

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1 A. Yes.

2 Q. Okay. Does the Dependence  
 3 Effect include within its scope individuals  
 4 who deliberately misused an opioid medication  
 5 knowing that they were not using it for its  
 6 intended indication; for example, crushing  
 7 it, snorting it for a high, for euphoria,  
 8 instead of to treat an indicated pain  
 9 condition?

10 A. Yes.

11 Q. So the third of your triagrid  
 12 {phonetic} is the Gateway Effect, capital G,  
 13 capital E.

14 So in -- on page 86 of your  
 15 report, Exhibit 1, you describe the Gateway  
 16 Effect as -- you say, "The trajectory to  
 17 addiction begins with exposure." Is that  
 18 right?

19 A. That's right.

20 Q. Okay. So have you ever  
 21 tested -- well -- actually, strike that.

22 I wanted to ask one more  
 23 question about the Dependence Effect.

24 Have you ever published the  
 25 theory of the Dependence Effect in any

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1 peer-reviewed, scientific journal?

2 A. I haven't -- I haven't -- I  
haven't specifically used that terminology,  
but in the JAMA article that we published on  
buprenorphine prescribing, we do talk about  
the exposure and the millions of people  
exposed to opioids through a medical  
prescription, the vast majority of whom  
probably are opioid dependent.

10 Q. And have you specifically used  
11 the terminology of the Tsunami Effect,  
12 capital T, capital E, in any peer-reviewed  
13 scientific journal?

14 A. No.

15 Q. Have you ever tested the  
16 Gateway Effect, going to the third leg, to  
17 quantify what percentage of persons  
ultimately addicted to illegal heroin, or  
fentanyl, were individuals who started out  
purely with no substance abuse history and  
whose initial exposure was via a medically  
appropriate prescription of an opioid  
medication?

24 MR. ARBITBLIT: Object to form.

25 THE WITNESS: Are you asking me

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1 if I've personally done that

2 quantitative research?

3 QUESTIONS BY MR. TSAI:

4 Q. Yes.

5 A. I have not.

6 Q. Have you ever used the specific  
7 terminology of the Gateway Effect and  
8 published that observation in any  
9 peer-reviewed scientific journal?

10 A. No.

11 Q. Have you ever tested the  
12 Gateway Effect phenomenon to rule out the  
13 inclusion of individuals who deliberately  
14 committed a crime in obtaining and using  
15 opioids?

16 A. I wouldn't rule out those  
17 individuals.

18 Q. Okay. So the Gateway Effect,  
19 as you envision it, as you define it, does  
20 include within its scope persons, including  
21 persons in Cuyahoga and Summit County, who  
22 deliberately committed a crime in obtaining  
23 and using opioids?

24 A. Yes.

25 Q. Does the Gateway Effect include

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1 within its scope individuals who deliberately  
2 misused a prescription opioid medication  
3 knowing that medication was not prescribed to  
4 them?

5 A. Yes.

6 Q. Does the Gateway Effect include  
7 within its scope individuals who deliberately  
8 misused a prescription opioid medication  
9 knowing it -- knowing that they were using it  
10 contrary to its intended indication and  
11 approved indication, for example, to get a  
12 high instead of treating pain?

13 A. So I would like to go back and  
14 amend what I said previously about the  
15 Gateway Effect and refer to my report, which  
16 on page 86, specifically says that the  
17 Gateway Effect describes those individuals  
18 who became exposed and addicted, including  
19 individuals who turned from prescription  
20 opioids to illicit sources of opioids such as  
21 heroin.

22 So what I'm -- the group I'm  
23 referring to in the Gateway Effect is, in  
24 fact, those individuals who started with a  
25 medical prescription and then became addicted

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1 through that medical prescription, as  
2 distinct from the Tsunami Effect, which is  
3 those individuals who -- which includes those  
4 individuals who used an opioid not  
5 necessarily prescribed to them.

6 Q. Okay. So the -- you know, the  
7 beginning bound of the set of individuals  
8 that you define as within the Gateway Effect  
9 are those individuals who received a  
10 prescription directly from a doctor?

11 A. Yes, and thank you for allowing  
12 me the opportunity to clarify that.

13 Q. So the Gateway theory posits a  
14 particular direction of events: First,  
15 prescription opioids prescribed by a doctor,  
16 and then later illegal heroin or street  
17 fentanyl addiction; is that right?

18 A. Not necessarily.

19 So that individual -- so you're  
20 right in the sense that it posits an  
21 individual who began with a prescription of  
22 an opioid from a doctor, but it -- and it  
23 could include those individuals who then turn  
24 to illicit sources of heroin, but it also  
25 includes those individuals who become

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1       addicted in an ongoing matter -- manner using  
 2       the opioids prescribed by that doctor.  
 3           Q.     Have you ever tested whether  
 4       the Gateway Effect is confounded by  
 5       individuals who had already used heroin  
 6       before prescription opioid medications?

7           MR. ARBITBLIT:   Object to form.

8           THE WITNESS:   Well, that's  
 9       something that the McCabe article  
 10      looked at, and I think one of the  
 11      salient findings there is it's really  
 12      the combined effect of access to  
 13      nonmedical opioids, plus medical use,  
 14      that confers risk. It's not one or  
 15      the other in isolation, and both of  
 16      those individual groups can become  
 17      addicted.

18           So people can get addicted  
 19      entirely through a medical  
 20      prescription and not engage in  
 21      nonmedical use. They can engage in  
 22      nonmedical use and then also be  
 23      exposed medically; thus compounding  
 24      their risk.

25

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1       QUESTIONS BY MR. TSAI:

2           Q.     So you would rely on the McCabe  
 3       study's findings in regard to those groups  
 4       that you mentioned?

5           MR. ARBITBLIT:   Object to form.

6           THE WITNESS:   No, I'm not  
 7       relying on the McCabe study findings.  
 8       As I said before, I've done my own  
 9       qualitative research, and I've also --  
 10      I have vast experiential knowledge of  
 11      this problem from the many patients  
 12      I've treated in almost, you know, two  
 13      decades.

14           So I have seen the pattern of  
 15      opioid addiction as it has occurred in  
 16      those individuals.

17       QUESTIONS BY MR. TSAI:

18           Q.     Does the Gateway Effect include  
 19      within its scope individuals who had first  
 20      used heroin before they used prescription  
 21      opioids?

22           A.     No.

23           Q.     And how would you know for a  
 24      particular person in Cuyahoga or Summit  
 25      County with opioid use disorder that medical

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1       history, that sequence?  
 2           MR. ARBITBLIT:   Object to form.  
 3           THE WITNESS:   There are good  
 4       national data that have surveyed  
 5       individuals asking them about which --  
 6       individuals who have become addicted  
 7       to opioids, asking them which opioid  
 8       they started with, and over 80 percent  
 9       of individuals report that they  
 10      started with a prescription opioid.

11       QUESTIONS BY MR. TSAI:

12           Q.     And those -- that statistic  
 13      includes nonmedical use of prescription  
 14      opioids?

15           A.     Yes, it does, but it also  
 16      includes medical use of prescription opioids.

17           Q.     Have you ever tested whether  
 18      the Gateway Effect is confounded by  
 19      individuals who had already deliberately  
 20      misused or abused other drugs before any  
 21      medical opioid prescription?

22           A.     There are those cases, and I  
 23      have treated those individuals, and to me  
 24      that doesn't mitigate the problem of  
 25      addiction through an opioid prescription.

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1       So, for example, I've had many  
 2       patients who were in recovery from an  
 3       addiction to something else, who then got  
 4       exposed to an opioid through a medical  
 5       prescription and became addicted to that  
 6       opioid or relapsed to their other substance  
 7       who otherwise, I believe, would not have done  
 8       so were it not for the unnecessary exposure  
 9       to that opioid through a medical  
 10      prescription.

11           Q.     And individuals with a history  
 12      of substance abuse, and certainly a history  
 13      of diagnosed substance use disorder, are at a  
 14      higher risk of substance abuse disorder; do  
 15      you agree?

16           MR. ARBITBLIT:   Object to form.

17           THE WITNESS:   We do know based  
 18      on retrospective, epidemiologic  
 19      studies that patients with a personal  
 20      history of substance use disorder are  
 21      at increased risk to develop an opioid  
 22      addiction through a medical  
 23      prescription of opioids, yes.

24       QUESTIONS BY MR. TSAI:

25           Q.     So you would agree that for

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1 individuals who reside in Cuyahoga and Summit  
 2 County with opioid use disorder, an important  
 3 piece of information to know is their history  
 4 of substance abuse disorder and substance use  
 5 history?

6 MR. ARBITBLIT: Object to form.

7 THE WITNESS: I don't really  
 8 consider that that important a piece  
 9 of history.

10 QUESTIONS BY MR. TSAI:

11 Q. So despite testifying that  
 12 epidemiology shows that patients with a  
 13 personal history of substance use disorder  
 14 are at an increased risk to develop an opioid  
 15 addiction through a medical prescription of  
 16 opioids, you wouldn't want to know whether  
 17 any particular individual in Cuyahoga and  
 18 Summit Counties had such a personal history  
 19 of substance abuse disorder?

20 MR. ARBITBLIT: Object to form.

21 Argumentative.

22 THE WITNESS: To me what's much  
 23 more relevant is that they're  
 24 currently addicted to opioids. I  
 25 don't consider their past history to

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1 inform that problem.  
 2 Furthermore, we know that many  
 3 people without a past history of  
 4 addiction can get addicted to opioids  
 5 through a doctor's prescription.

6 QUESTIONS BY MR. TSAI:

7 Q. Okay. And since your opinion  
 8 isn't -- individual's personal history of  
 9 substance use disorder is not information  
 10 that you would need to know, you did not  
 11 review any such information for any actual  
 12 individual with opioid use disorder in  
 13 Cuyahoga and Summit County; am I right?

14 MR. ARBITBLIT: Object to form.

15 Object to the preface.

16 THE WITNESS: I did not review  
 17 any individual patient's history.

18 QUESTIONS BY MR. TSAI:

19 Q. So based upon your clinical  
 20 experience, can you walk us through the steps  
 21 between a person receiving a prescription  
 22 from a doctor for an opioid medication and  
 23 the ultimate outcome of going out to a street  
 24 dealer and seeking illegal, nonprescribed,  
 25 nonregulated heroin or fentanyl?

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1 How does that -- how does the  
 2 Gateway Effect play out in your mind from  
 3 prescription to going out into a street  
 4 dealer?

5 MR. ARBITBLIT: Object to form.

6 Vague. Compound.

7 THE WITNESS: An individual  
 8 presents in a medical clinic with pain  
 9 and is prescribed opioids by that  
 10 doctor.

11 The doctor has been misled by  
 12 false promotional statements on the  
 13 part of defendants to believe that  
 14 there are benefits to the use of  
 15 opioids used long term in the  
 16 treatment of pain, despite the absence  
 17 of evidence for that. And that doctor  
 18 has also been told that the risks are  
 19 very small for addiction as long as  
 20 that individual is being prescribed  
 21 opioids for a pain condition.

22 So that well-intentioned and  
 23 compassionate doctor, who is trying to  
 24 do the right thing, will continue that  
 25 opioid prescription and even increase

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1 the dose over time as that patient  
 2 inevitably develops tolerance.  
 3 That doctor, furthermore,  
 4 having been misled by the defendants  
 5 to believe that no dose is too high,  
 6 will continue to escalate that dose  
 7 over months to years until that  
 8 patient is at dangerously high doses  
 9 of opioids and at risk for all kinds  
 10 of morbidity and mortality, including  
 11 the risk of addiction.

12 And eventually that individual,  
 13 who is on very high doses of opioids,  
 14 has neurologic changes in their brain  
 15 such that if they -- they begin to  
 16 experience withdrawal often between  
 17 doses, so intradose withdrawal.

18 They have the sensation that  
 19 was validated by their doctor, but  
 20 which is probably not the case, that  
 21 the -- they need the opioids to treat  
 22 their pain when, in fact, taking the  
 23 opioids is most likely just treating  
 24 withdrawal from the last dose, but the  
 25 physiology and the pain of withdrawal

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1       drives that individual to then become  
 2       very preoccupied with their pain, very  
 3       preoccupied with the opioids, spending  
 4       more and more time at the doctor's  
 5       office with pain complaints, reporting  
 6       that the opioids are no longer  
 7       working, because they don't work in  
 8       most cases for chronic pain.

9           And again, the compassionate  
 10      doctor, being told that no dose is too  
 11      high, continues to escalate until that  
 12      individual is at a very, very high  
 13      dose, and that individual spends  
 14      almost all of their time possibly  
 15      going to the emergency room to try to  
 16      get more opioids to help with their  
 17      worsened pain and their withdrawal and  
 18      their tolerance, to the point that  
 19      that individual has developed a  
 20      full-blown opioid addiction within the  
 21      context of medical care.

22           Now, should it happen that at  
 23      some point that doctor retires or that  
 24      doctor gets ill and can't treat that  
 25      person anymore or that individual

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1       moves to another region or the doctor  
 2       moves to another region and then that  
 3       individual can no longer obtain the  
 4       opioids through the prescription of  
 5       that -- of that doctor, then sometimes  
 6       individuals will look to alternative  
 7       and illicit sources of opioids. And  
 8       to their mind -- in their mind, they  
 9       are treating their pain when they have  
 10      also developed an opioid use disorder.

11      QUESTIONS BY MR. TSAI:

12           Q.     Do you agree with -- let me  
 13      know if you agree or disagree with this.

14           When individuals become  
 15      addicted to an opioid, they remain human  
 16      beings?

17           A.     Of course I agree with that.

18           Q.     And true or false, an  
 19      opioid-addicted person is just a mindless  
 20      zombie?

21           MR. ARBITBLIT: Object to form.

22           THE WITNESS: I don't even know  
 23      how -- that's really offensive, and I  
 24      don't even know how to respond to  
 25      that.

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1      QUESTIONS BY MR. TSAI:

2           Q.     So you disagree with that  
 3      statement?

4           MR. ARBITBLIT: Object to form.

5           THE WITNESS: I disagree with  
 6      that statement.

7      QUESTIONS BY MR. TSAI:

8           Q.     So at the end of the day, do  
 9      you agree that a person who leaves his or her  
 10     house, goes to the bad part of town, turns to  
 11     a street drug dealer to buy illegal heroin  
 12     has assumed an extraordinary risk?

13           MR. ARBITBLIT: Object to form.

14           THE WITNESS: I would  
 15      respectfully say that I would like to  
 16      take the time to educate you about the  
 17      disease of addiction, because I don't  
 18      think you understand it; that people  
 19      with addiction lose voluntary control  
 20      over their ability to choose or not  
 21      choose to use that substance; that  
 22      they're driven by an intense  
 23      physiologic need for the substance due  
 24      to the neurobiological changes,  
 25      essentially the brain damage incurred

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1       by exposure to that substance.

2      QUESTIONS BY MR. TSAI:

3           Q.     Do you agree that a person who  
 4      leaves his house, goes to the bad part of  
 5      town, seeks out a drug dealer and buys  
 6      illegal heroin, has decided to break the law?

7           MR. ARBITBLIT: Object to form.

8           THE WITNESS: No, not at all.  
 9           In fact, I don't think there's the  
 10     capacity for decision-making anymore  
 11     for that individual.

12           That individual is driven by  
 13      their disease. The lying, cheating,  
 14      stealing and illegal activity that  
 15      comes with addiction are symptoms of  
 16      the disease of addiction.

17      QUESTIONS BY MR. TSAI:

18           Q.     So for an individual who has  
 19      been charged with, say, a heroin-related drug  
 20      crime, do you believe in your opinion that  
 21      they have a defense, just to say, "Well, I've  
 22      received a prescription opioid medication"?

23           MR. ARBITBLIT: Objection.  
 24           Calls for a legal conclusion.

25           THE WITNESS: That's very

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1 hypothetical. I would really want to  
 2 know the details of that specific  
 3 scenario.

4 QUESTIONS BY MR. TSAI:

5 Q. Okay.

6 A. So someone charged with a  
 7 heroin crime could include a bunch of  
 8 different types of heroin-related crimes.

9 Q. Okay. So you agree that the  
 10 circumstances matter; the circumstances of an  
 11 individual's use or abuse of heroin do matter  
 12 in determining his or her fault?

13 MR. ARBITBLIT: Object to form.

14 Calls for a legal conclusion.

15 THE WITNESS: I don't really  
 16 understand the question.

17 QUESTIONS BY MR. TSAI:

18 Q. Okay. Do you believe if a  
 19 criminal defendant who was charged in  
 20 Cuyahoga and Summit County with a heroin drug  
 21 crime took the stand and said, "You know,  
 22 according to the Gateway theory, I'm really  
 23 not at fault; it's the prescription drug  
 24 companies," do you think that that was --  
 25 that's an acceptable defense?

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1 MR. ARBITBLIT: Object to form.  
 2 Calls for speculation for a legal  
 3 conclusion.

4 THE WITNESS: I believe that if  
 5 that individual has the disease of  
 6 addiction, it mitigates any fault they  
 7 might have in some kind of criminal  
 8 litigation that they're involved in.

9 QUESTIONS BY MR. TSAI:

10 Q. Okay. And then the extent of,  
 11 in your view, the mitigation of their fault,  
 12 what would it depend on?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: Well, it would  
 15 depend on -- I mean, it would -- it  
 16 would involve many factors. It would  
 17 depend on the severity of their  
 18 disease of addiction. It would depend  
 19 on the severity of the crime itself.

20 So there would be lots of  
 21 mitigating factors.

22 QUESTIONS BY MR. TSAI:

23 Q. All right. And for any  
 24 individuals in Cuyahoga and Summit Counties,  
 25 have you reviewed information about the

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1 severity of their opioid-related,  
 2 heroin-related crimes, fentanyl-related  
 3 crimes or the degree of their opioid use  
 4 disorder?

5 A. Not for specific individuals.

6 Q. Okay. So you use the term  
 7 "intervention" many times in your report.

8 A. Okay.

9 Q. Do you agree that there are  
 10 many points of intervention for someone using  
 11 prescription opioid medications in terms of  
 12 catching, monitoring the symptom of addiction  
 13 after they start using the medication?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: Who would be the  
 16 person doing the intervention?

17 QUESTIONS BY MR. TSAI:

18 Q. Well, let me give you an  
 19 example.

20 So do you agree that if a  
 21 person using prescription opioid medications  
 22 herself notices signs of addiction, craving,  
 23 for example, she can tell her doctor?

24 A. I disagree that that would  
 25 happen in the real world because patients who

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1 become addicted are commonly unaware of  
 2 becoming addicted. That's often the way  
 3 mental illness works in general, not just for  
 4 addiction but other mental illnesses as well.  
 5 Because the diseased organ is the brain, we  
 6 lose self-awareness and an ability to  
 7 objectively see ourselves.

8 So in the real world, it would  
 9 be unusual for a patient to present and say  
 10 to her doctor, "I'm having craving."

11 Also I would argue that  
 12 that term "craving" is a very loaded term.  
 13 It's very stigmatized. It's in the same  
 14 bucket as the term you used earlier  
 15 "addicts," and patients would typically not  
 16 use stigmatizing terms to refer to  
 17 themselves, especially in a medical context.

18 I would also say that patients  
 19 who are becoming addicted through a doctor's  
 20 prescription have a very strong narrative  
 21 around treating their pain. So they do not  
 22 experience craving the way that somebody who  
 23 self-identifies as addiction might talk about  
 24 craving. What they experience is physical  
 25 pain.

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1 Q. Well, let's talk about someone  
 2 around a person with opioid use disorder.  
 3 Do you agree that if a  
 4 coworker, a parent, a sibling, a friend,  
 5 other family members notice, they can  
 6 intervene?

7 MR. ARBITBLIT: Object to form.

8 THE WITNESS: When you say  
 9 "they can intervene," can you give an  
 10 example of something that they might  
 11 do?

12 QUESTIONS BY MR. TSAI:

13 Q. Sure.

14 If they notice signs and  
 15 symptoms of opioid addiction, can they --  
 16 you'd agree they can go to the person taking  
 17 the opioids and say, "I think you have a  
 18 problem, we should do something about it"?

19 A. Yes, they could do that.

20 Q. You've seen that happen?

21 A. Yes, I have.

22 Q. Okay. And in your report, this  
 23 is on page 95, you say, "Addiction treatment  
 24 should be offered within every hospital,  
 25 clinic, emergency room, jail and drug court,

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1 et cetera, across America. Meeting patients  
 2 where they are has become a mantra for the  
 3 field."

4 So do you agree that in the  
 5 lifecycle of opioid use disorder, there are  
 6 many meetings points, many touch points,  
 7 where opioid use disorder can be noticed, can  
 8 be caught and can be treated?

9 MR. ARBITBLIT: Object to form.

10 THE WITNESS: As applies to  
 11 this case of the opioid epidemic, I  
 12 think it has been and continues to be  
 13 extremely difficult to intervene,  
 14 especially in the context of the  
 15 patient with pain being prescribed  
 16 opioids by a compassionate doctor and  
 17 a misinformed doctor to treat their  
 18 pain.

19 Because even as the disease of  
 20 addiction evolves in that context, the  
 21 patient doesn't recognize that he or  
 22 she is becoming addicted, and the  
 23 doctor who has been miseducated due to  
 24 false promotions on the part of  
 25 defendants doesn't appreciate that

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1 patients are at high risk for  
 2 addiction, even in the context of  
 3 being treated for their pain.

4 So it makes it extremely  
 5 difficult to intervene in that context  
 6 compared to, for example, if that  
 7 person is using heroin that they got  
 8 on the street corner.

9 QUESTIONS BY MR. TSAI:

10 Q. Is one important factor in the  
 11 extent or the rate of opioid use disorder the  
 12 number of times folks, you know, family,  
 13 friends, doctors, nurses, try to or do  
 14 intervene to bring the person into treatment?

15 MR. ARBITBLIT: Object to form.

16 THE WITNESS: I don't  
 17 understand your question.

18 QUESTIONS BY MR. TSAI:

19 Q. Is that an important factor --  
 20 MR. ARBITBLIT: Objection.

21 QUESTIONS BY MR. TSAI:

22 Q. -- the number of times that  
 23 people try to intervene to stop or to treat  
 24 the progression into opioid use disorder?

25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: An important  
 2 factor for what?

3 QUESTIONS BY MR. TSAI:

4 Q. For the rate of ultimate opioid  
 5 use disorder or the --

6 MR. ARBITBLIT: Object to form.  
 7 Incomplete hypothetical.

8 THE WITNESS: I guess I'm  
 9 not -- I'm still not understanding the  
 10 question. I'm sorry.

11 QUESTIONS BY MR. TSAI:

12 Q. Well, do you agree that there  
 13 are many touch points where intervention  
 14 could have an effect on someone with opioid  
 15 use disorder?

16 MR. ARBITBLIT: Object to form.

17 THE WITNESS: I'm always  
 18 hopeful that there are points where we  
 19 could intervene and help a person with  
 20 opioid use disorder. That's -- my  
 21 entire professional life is dedicated  
 22 toward helping people with addiction.  
 23 (Lembke Exhibit 3 marked for  
 24 identification.)

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1 QUESTIONS BY MR. TSAI:

2 Q. So if we could get Tab 5, and  
 3 this will be Exhibit 3. This is the Edlund  
 4 study. I would like to ask you a few  
 5 questions about that.

6 So just turning your attention  
 7 to page 5 of the Edlund study?

8 A. Oh, page 5? Okay.

9 Q. This is one of the articles  
 10 that you cite in your report, correct?

11 A. Yes.

12 Q. Okay. If you look under  
 13 Results, the first paragraph, and then the  
 14 third sentence I'll read.

15 It says, "When opioids were  
 16 prescribed, low dose/acute use, 15.9 percent  
 17 of total sample, and medium dose/acute use,  
 18 14.7 of total sample, were by far the most  
 19 common types of opioid use, and high  
 20 dose/chronic use was the least common,  
 21 0.1 percent of the total sample."

22 Do you see that?

23 A. Yes, I do.

24 Q. Okay. Any reason to disagree  
 25 with that finding?

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1 A. No.

2 Q. And then if you look at the  
 3 next paragraph, the last sentence, they  
 4 actually break that down and translate that  
 5 into actual individuals that were part of the  
 6 study.

7 So am I reading this right that  
 8 out of the 568,640 persons in this study  
 9 sample, only 23 used opioids in high doses  
 10 for more than 91 days?

11 MR. ARBITBLIT: Misstates the  
 12 record.

13 You're just reading it wrong,  
 14 Counsel.

15 THE WITNESS: It says 23 out of  
 16 378 are high dose.

17 QUESTIONS BY MR. TSAI:

18 Q. So counting the number of  
 19 individuals in the sample who were in the  
 20 high dose/chronic subset, that's 23; am I  
 21 reading that right?

22 MR. ARBITBLIT: That's the  
 23 number with opioid use disorder,  
 24 Counsel, not the number who used it.

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1 QUESTIONS BY MR. TSAI:

2 Q. Oh, so it's even smaller. So  
 3 23 is the number of persons studied in the  
 4 sample in the high dose/chronic subset who  
 5 were found to have opioid use disorder.

6 Am I reading that right?

7 A. That's right, yes.

8 Q. Okay.

9 MR. TSAI: So can we get Tab 6,  
 10 please?

11 (Lembke Exhibit 4 marked for  
 12 identification.)

13 QUESTIONS BY MR. TSAI:

14 Q. So exhibit next in order --

15 MR. ARBITBLIT: Before you move  
 16 on, Counsel, for completeness, the  
 17 odds ratio for those in that category  
 18 was 122.45, reading from page 5, the  
 19 last sentence at the bottom paragraph,  
 20 "For high dose/chronic odds ratio  
 21 equals 122.45, 95 percent confidence  
 22 interval, 72.79 to 205.99, P value,  
 23 0.001."

24 MR. TSAI: For the record, I  
 25 object to counsel's testimony. Again,

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1 this is taking up time. It's  
 2 inappropriate.

3 MR. ARBITBLIT: It's not  
 4 inappropriate. It's allowed under  
 5 Rule 106. Read it and tell me if you  
 6 disagree after you've read it.

7 MR. TSAI: I think it's not  
 8 allowed under the deposition protocol,  
 9 and I'll reserve rights. This is the  
 10 second time it's happened, so...

11 QUESTIONS BY MR. TSAI:

12 Q. So exhibit next in order is the  
 13 National Academy of Sciences Engineering and  
 14 Medicine study that you cited in your report.

15 You refer to it as the NASEM?

16 A. Uh-huh.

17 Q. Or NASEM study?

18 A. Yes.

19 Q. All right. This is a big  
 20 report, but I can -- we'll certainly focus  
 21 you on a particular page, which is -- if you  
 22 could turn to page -- it's Bates stamped  
 23 MDL\_EXP\_0003335. It's internal page 210 if  
 24 that makes it easier.

25 MR. ARBITBLIT: Are you giving

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1 copies?

2 THE WITNESS: 33 --

3 QUESTIONS BY MR. TSAI:

4 Q. Yeah, it's probably easier to

5 go to the internal page number, which is 210,

6 which is on the top, and the Bates number on

7 the bottom is 3335.

8 A. Yeah.

9 Okay.

10 Q. So if you could look at the

11 last paragraph on that page, I'll read it.

12 It says, "It is important to acknowledge that

13 an overwhelming majority of people who use

14 prescription opioids do not continue to use

15 them chronically," and it has a citation to

16 Shah, et al., 2017, "and so are not at risk

17 of switching to heroin."

18 Do you see that?

19 A. Uh-huh.

20 Q. Do you have any basis to

21 disagree with that statement?

22 Well, first of all, do you

23 agree with that statement?

24 A. I guess I would be curious to

25 know what they -- how they quantified or

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1 defined "overwhelming majority."

2 Q. Did you undertake any

3 quantitative analysis of the data underlying

4 this NASEM study that you've cited?

5 A. Give me a moment.

6 So according to Mojtabai, et

7 al., which is in my report on page 11, I'll

8 read, quote, "Of all opioid users in 2013 and

9 2014, 79.4 percent were long-term users

10 compared with 45.1 percent in 1999 to 2000."

11 And then I go on to say in my

12 own words, "The increase in long-term use is

13 important because increased duration of use

14 is also directly correlated with risk of

15 addiction," at which point I cite the Edlund

16 study, which you've given me here.

17 Q. Okay. Have you reviewed any of

18 the data or conducted any of your own

19 analysis of the information that underlies

20 the NASEM conclusion that the overwhelming

21 majority of people who use prescription

22 opioids do not continue to use them

23 chronically and so are not at risk of

24 switching --

25 A. Based on --

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1 Q. -- to using heroin?

2 A. Yeah. Based on my review of

3 the literature, I would disagree with that

4 statement, and I cited one article for you

5 that's in my report. So I disagree with that

6 statement.

7 Q. And do you have a basis based

8 upon what the authors of the -- what the

9 National Academy of Sciences Engineering and

10 Medicine in 2017 base their conclusion on?

11 MR. ARBITBLIT: Objection.

12 Speculation.

13 THE WITNESS: I did not

14 exhaustively review which articles

15 they reviewed to form this conclusion,

16 but I have read over 400 articles in

17 forming my opinion, and my opinion

18 disagrees with that statement there.

19 QUESTIONS BY MR. TSAI:

20 Q. So you -- it's fair to say that

21 the National Academy of Sciences and

22 Engineering and Medicine, their view of the

23 Gate -- what you call the Gateway phenomenon

24 is that the minority of people using

25 prescription opioids are at risk of switching

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1 over to illegal street heroin?

2 A. As I've stated in my report, I

3 believe that somewhere between 8 and

4 40 percent of individuals who are prescribed

5 an opioid for a medical condition go on to

6 develop an opioid use disorder.

7 That opioid use disorder may

8 include individuals who continue with the

9 prescription opioid and individuals who

10 switched to heroin.

11 So, again, over --

12 quote/unquote "overwhelming majority," no, I

13 would -- I guess I would want to review that

14 Shah article and read it in more depth.

15 MR. TSAI: Tab 7, please.

16 (Lembke Exhibit 5 marked for

17 identification.)

18 QUESTIONS BY MR. TSAI:

19 Q. So next exhibit in order is the

20 Muhuri article that you cite in your report.

21 I would like to ask you a few questions about

22 that.

23 So if you could turn to the

24 first page of the Muhuri article that's been

25 handed to you, and I first want to ask

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1 about -- turn your attention to the abstract.

2 Do you see the abstract in the  
3 black box on page 1?

4 A. Yes, I do. I'm just trying to  
5 find it in my report.

6 Q. It's on page 85 --

7 A. Great. Thank you.

8 Q. -- of your report.

9 So I'll just read this

10 conclusion of the authors of the Muhuri  
11 article that you cite. They state, "However  
12 the vast majority of NMPR users have not  
13 progressed to heroin use. Only 3.6 percent  
14 of NMPR initiates had initiated heroin use  
15 within the five-year period following first  
16 NMPR use."

17 Do you see that?

18 A. Yes, I do.

19 Q. And what is NM -- NMPR is  
20 nonmedical pain relief?

21 A. Reliever.

22 Q. Reliever?

23 A. Yeah.

24 Q. Okay. So just focusing on  
25 individuals who had used the opioid

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1 medications they were prescribed for  
2 nonmedical reasons such as getting a high,  
3 the majority of folks who used prescription  
4 opioids nonmedically were found not to  
5 progress to heroin use.

6 Is that -- am I reading that  
7 finding correctly?

8 MR. ARBITBLIT: Object to form.

9 THE WITNESS: Yes.

10 QUESTIONS BY MR. TSAI:

11 Q. Okay. And do you agree with  
12 this finding?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: Yes, I do with  
15 this finding, but I think one of the  
16 major points of the Muhuri article are  
17 that 80 percent of persons who began  
18 using heroin started with a  
19 prescription opioid.

20 Also, I would say that

21 although --

22 QUESTIONS BY MR. TSAI:

23 Q. And that 80 percent figure --

24 MR. ARBITBLIT: Let her finish.

25 Don't interrupt. Part of the

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1 protocol.

2 THE WITNESS: It's okay.

3 QUESTIONS BY MR. TSAI:

4 Q. Great.

5 So the 80 percent figure, this  
6 is on page 85 of your report, those are  
7 persons, individuals, who had used  
8 prescription opioids nonmedically before  
9 initiating illegal heroin use, correct?

10 A. Yes, but I object to your  
11 example, if I'm allowed to object, of --

12 Q. You're not allowed to object.

13 A. Oh, I'm not allowed to?

14 MR. ARBITBLIT: She's allowed  
15 to finish her answer.

16 MR. TSAI: The lawyers are --

17 MR. ARBITBLIT: She's allowed  
18 to finish her answer.

19 THE WITNESS: Yes. So every  
20 time you've mentioned nonmedical use  
21 of prescription opioids, you've used  
22 as the example to get high, and I  
23 would say that the vast -- or a large  
24 percentage, in my experience and based  
25 on my research, are not, in fact,

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1 using the prescription opioid to get  
2 high.

3 There are many forms of misuse,  
4 for example, taking more than a doctor  
5 prescribed in order to relieve pain.

6 So I just wanted to say that.

7 QUESTIONS BY MR. TSAI:

8 Q. If you could then turn to  
9 page 14 of the Muhuri article, and that's the  
10 internal page 14 of 15. The Bates number at  
11 the bottom is -- ends in 6042.

12 And do you see the section  
13 called "Discussion" on that page?

14 A. Yes.

15 Q. Okay. So if you go down to the  
16 third from the last sentence, I'll read it.  
17 "Although the findings indicate that NMPR  
18 use," again, that's nonmedical pain reliever  
19 use, "is a common step on the pathway to  
20 heroin initiation, most NMPR users do not  
21 progress to heroin use."

22 Do you see that?

23 A. Yes.

24 Q. Okay. And do you have any  
25 basis to disagree with that finding?

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1 A. No.  
 2 Q. And they use the term it's "a  
 3 common step on the pathway to heroin use."  
 4 What are the other steps on the  
 5 pathway to heroin initiation, other than  
 6 beginning with opioid -- prescription  
 7 opioids?

8 A. Well, I would say that this  
 9 specifically speaks to nonmedical use of  
 10 prescription opioids, and I think medical use  
 11 of prescription opioids is also a common  
 12 pathway to heroin addiction.

13 So there are many people who  
 14 take their opioids just as prescribed and get  
 15 addicted in that process.

16 Q. Any other pathways to heroin  
 17 addiction?

18 A. Yes. There are people who  
 19 obtain heroin as their first opioid, but it's  
 20 much less common than folks who start with a  
 21 prescription opioid.

22 Q. So am I stating this conclusion  
 23 correctly, that the finding of the Muhuri  
 24 article that you cite is that the majority of  
 25 prescription opioid nonmedical users actually

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1 do not walk through the gateway to illegal  
 2 heroin?  
 3 MR. ARBITBLIT: Object to form.  
 4 QUESTIONS BY MR. TSAI:  
 5 Q. They turn away or otherwise  
 6 take another path?  
 7 A. That is what it says here, yes.  
 8 Q. Okay. So then going back to  
 9 page 1, the first page of the Muhuri article,  
 10 in the introduction section, if you look down  
 11 to the second paragraph, the authors observe  
 12 that this progression from opioid --  
 13 prescription opioid medications to illegal  
 14 heroin may result simply because heroin may  
 15 be cheaper or easier for them to get in some  
 16 locations.

17 Do you see that?

18 A. Is that here on this first  
 19 page?

20 Q. Yeah. It's the first page --  
 21 I'm sorry, I have a different -- right.  
 22 Sorry.

23 It is the second page of your  
 24 exhibit. The Bates number ends in 6028, and  
 25 it's the first full paragraph on that page.

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1 It says, "This progression may result simply  
 2 because heroin may be cheaper or easier for  
 3 them to get in some locations."

4 Do you see that?

5 A. Yes.

6 Q. Okay. Do you have any -- did  
 7 you review any information or do any analysis  
 8 to determine whether this reason for switched  
 9 to illegal heroin, that it's cheaper or  
 10 easier to get, whether that applied --  
 11 applies in Cuyahoga or in Summit Counties?

12 A. No.

13 Q. Okay.

14 MR. TSAI: Could we get Tab 8,  
 15 please?

16 MR. ARBITBLIT: Okay. Counsel,  
 17 I don't want to have a disagreement  
 18 with you about this, but I don't see  
 19 in our summary of the protocol  
 20 anything that would overrule Federal  
 21 Rule 106.

22 If you have something that you  
 23 think prevents from me reading for the  
 24 Rule of Completeness, I would like to  
 25 know specifically what it is.

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1 I don't want to do this to  
 2 cause animosity. I do think, based on  
 3 my own experience and the rule itself,  
 4 that anything that in fairness should  
 5 be read with the same document as  
 6 you've brought in to evidence should  
 7 be read, and that's what the Rule of  
 8 Completeness, Federal Rule 106 says.

9 If you have something that you  
 10 think specifically overrules that rule  
 11 in our deposition protocol, please let  
 12 me know what it is. Otherwise, I'm  
 13 going to do it again, and I don't want  
 14 to do it again and have a fight with  
 15 you. That's not my purpose.

16 MR. TSAI: We have a limited  
 17 time on the record. Suffice it to  
 18 say, I disagree.

19 MR. ARBITBLIT: You can  
 20 disagree, and you can reserve your  
 21 rights, but I'm just going to read one  
 22 sentence from the same Muhuri article  
 23 that says, "There are many plausible  
 24 explanations for this finding,  
 25 including the Gateway theory of drug

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1 use, that posits that the use of some  
 2 drugs may expose individuals to a  
 3 repertoire of biological and  
 4 behavioral factors that could  
 5 influence their future use of other  
 6 drugs."

7 And that's at MDL\_EXP\_0006043,  
 8 and you can reserve whatever rights  
 9 you feel you have. But I'm trying to  
 10 do this expeditiously. I think I've  
 11 taken up a total of about two minutes  
 12 of your time.

13 MR. TSAI: And not only do I  
 14 reserve rights, I very much object to  
 15 counsel's eating up the time on the  
 16 record with his testimony and  
 17 colloquy, which is prohibited under  
 18 the deposition protocol expressly, so  
 19 I want to move on.

20 Can we get Tab 8, please?

21 (Lembke Exhibit 6 marked for  
 22 identification.)

23 QUESTIONS BY MR. TSAI:

24 Q. So I want to talk about the  
 25 Compton article that you cite in your report.

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1 This will be exhibit next in order.

2 MR. TSAI: Let's get that  
 3 tabbed with the exhibit number.

4 QUESTIONS BY MR. TSAI:

5 Q. So if you could turn to  
 6 page 160 of the Compton article. This is a  
 7 New England Journal of Medicine article that  
 8 you've cited in your report. And then do you  
 9 see under the right-hand column the section  
 10 "Conclusions"?

11 A. Yeah.

12 Q. The second sentence, I'll read  
 13 it. The authors says, "Yet although the  
 14 majority of current heroin users report  
 15 having used prescription opioids nonmedically  
 16 before they initiated heroin use, heroin use  
 17 among people who use prescription opioids for  
 18 nonmedical reasons is rare, and the  
 19 transition to heroin use appears to occur at  
 20 a low rate."

21 Do you see that?

22 A. Uh-huh, I do.

23 Q. Do you have any reason to  
 24 disagree with this finding in the New England  
 25 Journal of Medicine?

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1 A. I don't.  
 2 Q. Okay. So there was an  
 3 interesting statement that caught my eye in  
 4 your report. It was page 58. You say,  
 5 "Contrary to what defendants claimed, opioid  
 6 painkillers are as addictive as heroin  
 7 purchased on a street corner, even when being  
 8 prescribed by a doctor for a legitimate pain  
 9 condition because the prescription opioids  
 10 have the same addictive effects on the  
 11 neurocircuitry of the brain."

12 Do you recall that?

13 A. Yes.

14 Q. The equivalent statement that  
 15 you made, I just want to test the boundaries  
 16 of that statement.

17 Do you agree that illegal  
 18 street heroin or fentanyl, for that matter,  
 19 is not clinically tested by the US FDA?

20 MR. ARBITBLIT: Object to form.

21 THE WITNESS: Well, fentanyl is  
 22 available in prescription form, so I  
 23 guess, what do you mean by "clinically  
 24 tested"?

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1 QUESTIONS BY MR. TSAI:

2 Q. I'm talking about illegal  
 3 street heroin where you go out to the corner  
 4 drug dealer and get illegal fentanyl that has  
 5 been synthetically manufactured by the  
 6 criminal gang in China, let's say.

7 Illegal street heroin and  
 8 fentanyl, they are not clinically tested by  
 9 the FDA, unlike prescription opioid  
 10 medications, correct?

11 A. That's correct, but can I --  
 12 fine, uh-huh.

13 Q. Do you agree that illegal  
 14 street heroin or illegal street fentanyl sold  
 15 by drug dealers on the street is not approved  
 16 by the FDA? It's not approved by the  
 17 government?

18 A. I would say that both of those  
 19 molecules, both heroin and fentanyl -- well,  
 20 fentanyl -- a form of fentanyl is approved by  
 21 the FDA and prescribed, and heroin is just  
 22 morphine with two acetyl groups added.

23 So the point I was trying to  
 24 make in my report is that when you consider  
 25 the way that these prescription opioids act

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1 on the brain compared to illicit opioids,  
 2 you're dealing with identical substances, and  
 3 that was the point that I was trying to make  
 4 with that statement.

5 Q. But if we're not just talking  
 6 about organic chemistry or pharmacology, you  
 7 agree that it's a very different context --  
 8 illegal street heroin or fentanyl is not  
 9 manufactured in a government-approved,  
 10 government-audited and inspected facility,  
 11 agree?

12 MR. ARBITBLIT: Object to form.

13 Compound.

14 THE WITNESS: Street heroin or  
 15 let's say street fentanyl could, in  
 16 fact, include versions of fentanyl  
 17 that have been FDA approved, if they  
 18 were diverted from that -- from a  
 19 legitimate source.

20 QUESTIONS BY MR. TSAI:

21 Q. And when you say "diverted,"  
 22 that means someone along the chain that -- it  
 23 gets into the hands of a drug dealer on the  
 24 street has committed a crime?

25 A. Yes.

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1 Q. Okay. And illegal street  
 2 heroin and fentanyl, it may be adulterated in  
 3 who knows what ways by the dealer, correct?  
 4 MR. ARBITBLIT: Object to form.  
 5 THE WITNESS: Yes, that's true.

6 QUESTIONS BY MR. TSAI:

7 Q. And when someone goes out into  
 8 the street, goes to a dealer and pays for  
 9 illegal street heroin or fentanyl, what they  
 10 get is not accompanied by a detailed warning  
 11 label or information about the risks and  
 12 benefits, correct, of that substance?

13 A. Yes, but that individual may  
 14 believe that they understand the risks and  
 15 benefits, for example, of fentanyl because  
 16 they have received it with a prescription.  
 17 And so they may come with that assumption to  
 18 the use of that illicit substance, you  
 19 know -- they're not just diverted pills but  
 20 also counterfeit pills.

21 So we have a whole population  
 22 of individuals who have received opioids  
 23 through a medical prescription who think that  
 24 they understand the effect of that opioid on  
 25 their body, and then if they get an

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1 adulterated version of that on the street,  
 2 that puts them at very high risk as a result  
 3 of their having received it with a medical  
 4 prescription.

5 Q. And have you reviewed any  
 6 information or have any basis to say that  
 7 that scenario that you've just outlined  
 8 occurred with any specific individual in  
 9 Cuyahoga or Summit County?

10 A. No, but that situation is  
 11 occurring nationally, and I believe that  
 12 Summit and Cuyahoga County have not been  
 13 excluded from that phenomenon.

14 Q. Okay. And when someone goes  
 15 out and buys illegal street heroin or  
 16 fentanyl on the street, that's not prescribed  
 17 by a doctor, not monitored by a health care  
 18 provider, agree?

19 A. I agree.

20 Q. Okay. So in all those ways,  
 21 you agree that prescription opioid  
 22 medications are not equivalent to street  
 23 heroin or street fentanyl, agree?

24 A. Yes.

25 Q. Okay. And I just want to

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1 explore your reasoning a little bit more.  
 2 If prescription opioids and  
 3 heroin are essentially equivalent in terms of  
 4 strength and potency at a cellular level,  
 5 that means that people who start on  
 6 prescription opioids and then turn to heroin,  
 7 they're not doing that in order to get a  
 8 stronger high; is that correct?

9 If they're equal in potency; is  
 10 that correct?

11 MR. ARBITBLIT: Object to form.

12 THE WITNESS: It would really  
 13 depend on the particular individual.  
 14 I would say that there are instances  
 15 in which that individual is not  
 16 looking for a stronger opioid but just  
 17 looking for an opioid to keep them  
 18 from going into painful withdrawal  
 19 when they can no longer get their  
 20 prescription opioid as their prior  
 21 source.

22 But it's also true that in the  
 23 natural disease of addiction involves  
 24 seeking out more potent forms over  
 25 time, and that's not to get high.

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1 That's to essentially avoid the  
 2 debilitating pain of withdrawal.  
 3 So again, I mean, you've  
 4 characterized this phenomenon  
 5 repeatedly as individuals going out to  
 6 get high as if this is some kind of  
 7 game or pleasure-seeking for them.  
 8 These individuals have a  
 9 disease of addiction, and it's not fun  
 10 for them. They're trying to stave off  
 11 the pain of withdrawal.

12 QUESTIONS BY MR. TSAI:

13 Q. It is a big step to go out and  
 14 take the risks of obtaining unregulated,  
 15 illegal street heroin and fentanyl, correct?

16 MR. ARBITBLIT: Object to form.

17 THE WITNESS: It is a big step,  
 18 and it speaks to the severity of their  
 19 suffering, that they're willing to  
 20 take that step.

21 QUESTIONS BY MR. TSAI:

22 Q. And in determining how and  
 23 whether the Gateway Effect applies in a  
 24 particular individual who takes that step, it  
 25 does depend on the individual circumstances,

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1 you agree?  
 2 MR. ARBITBLIT: Object to form.  
 3 THE WITNESS: What do you mean?  
 4 QUESTIONS BY MR. TSAI:  
 5 Q. It depends on the severity of  
 6 their particular condition?  
 7 MR. ARBITBLIT: Object to form.  
 8 THE WITNESS: There would be so  
 9 many variables involved in that.  
 10 QUESTIONS BY MR. TSAI:  
 11 Q. So if prescription opioids and  
 12 illegal heroin in your view are equal in  
 13 cellular potency and strength, then am I  
 14 right that what would trigger what you call  
 15 the Gateway Effect is the limitation, some  
 16 limitation, in the availability of  
 17 prescription opioids?

18 A. No.

19 Q. Okay. So is that one reason?  
 20 Is that one, say, pathway that accounts for  
 21 the Gateway Effect?

22 A. The limitation of prescription  
 23 opioids?

24 Q. Yes.

25 A. That is theoretically possible,

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1 and anecdotally people have reported that,  
 2 but I don't think there's a lot of data yet  
 3 to show that that's the case.  
 4 So, for example, in states  
 5 where limits have been set on opioid  
 6 prescribing, the result in those states has  
 7 been actually a decrease in opioid --  
 8 prescription opioid-related overdose deaths.

9 There's some question as to  
 10 whether in those states there may be an  
 11 increase in heroin-related overdose deaths  
 12 because individuals can no longer get their  
 13 prescription opioids, but I think that the  
 14 jury is still out on exactly what that  
 15 pathway is.

16 Q. Okay. So you can't offer a  
 17 conclusive opinion as to reliably rule out  
 18 that that is a common pathway that accounts  
 19 for the Gateway Effect, that being the  
 20 limitation of availability of prescription  
 21 opioids from a doctor?

22 MR. ARBITBLIT: Object to form.

23 QUESTIONS BY MR. TSAI:

24 Q. Correct?

25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: I guess I would  
 2 say I would need to know the specifics  
 3 of the case.

4 QUESTIONS BY MR. TSAI:

5 Q. Okay.

6 MR. ARBITBLIT: If you're ready  
 7 to move on, we've been going over an  
 8 hour, but if you're on same topic,  
 9 please complete what you're going  
 10 through.

11 MR. TSAI: So if I could -- can  
 12 we do Tab 2?

13 (Lembke Exhibit 7 marked for  
 14 identification.)

15 QUESTIONS BY MR. TSAI:

16 Q. So I'll come back to this, this  
 17 is your book --

18 A. Yes.

19 Q. "Drug Dealer MD." This is  
 20 exhibit next in order.

21 And I wanted to ask you if you  
 22 could turn to -- it is internal page 109.  
 23 And I'll also give you the Bates number. The  
 24 Bates number ends in 5643.

25 So if you look above the

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1 heading "opioid refugees," there's a  
 2 paragraph there, and let me just read,  
 3 starting with the second to the last  
 4 sentence.

5 "However, the relationship  
 6 between doctors' prescribing patterns and the  
 7 initiation of heroin use remains unclear."

8 Do you see that?

9 A. Uh-hmm.

10 Q. Is that still your opinion?

11 A. So, that was my opinion when I  
 12 wrote this because there was insufficient  
 13 evidence, but actually, where is that on  
 14 here? Because, you know, I completed this in  
 15 2014, and it takes two years until it  
 16 actually comes out.

17 And at the time that I wrote  
 18 this, I believed that -- what I was  
 19 specifically referring to there was whether  
 20 or not limits on opioid prescribing would  
 21 drive people to heroin use. So that's what I  
 22 meant with that statement.

23 Q. And are you -- is it still your  
 24 position that it is -- you can't offer a  
 25 conclusive opinion on that question?

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1 MR. ARBITBLIT: Object to form.

2 QUESTIONS BY MR. TSAI:

3 Q. That relationship?

4 A. I think that now I would say  
 5 that my opinion has changed vis-à-vis this  
 6 particular statement in the sense that this  
 7 is a very general statement, that "the  
 8 relationship between doctors' prescribing  
 9 patterns and the initiation of heroin use  
 10 remains unclear" because there's not a wealth  
 11 of evidence I've reviewed showing there's a  
 12 clear link between receiving an opioid  
 13 prescription with a doctor and being at  
 14 higher risk for progressing to heroin use.

15 Q. And does that evidence include  
 16 the studies that we went over just now, the  
 17 NASEM, the Muhuri, the Compton?

18 A. Yes.

19 Q. Okay. So going back to  
 20 Compton -- do you have that article, the  
 21 Compton article?

22 A. Yeah.

23 Q. If you could turn to page 156  
 24 of that article.

25 So in the left-hand column it's

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1 above that heading "Break." The heading  
 2 says, "Heroin use among people who use  
 3 prescription opioids nonmedically."

4 The sentence right before that,  
 5 I'll read it, it says, "Finally, these  
 6 differential properties and effects are  
 7 likely to interact with interindividual  
 8 variability in powerful complex and in  
 9 completely predictable ways so that some  
 10 persons who abuse prescription opioids could  
 11 find heroin less rewarding than prescription  
 12 opioids similarly rewarding or even more  
 13 rewarding."

14 Do you see that?

15 A. Yes, I do.

16 Q. And do you agree with that  
 17 statement?

18 A. I do.

19 Q. All right. For any individuals  
 20 in Cuyahoga and Summit Counties with opioid  
 21 use disorder, did you review any information  
 22 or have any other basis to say whether their,  
 23 as the New England Journal of Medicine put  
 24 it, individual variability was such that they  
 25 found heroin less similarly or more rewarding

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1 than prescription opioids?

2 A. I did not review individual  
 3 cases.

4 Q. Okay. And if we could turn to  
 5 the next page, 157, of the Compton article,  
 6 and the right-hand column, there they give  
 7 statistics that compare heroin use to use of  
 8 other substances.

9 So am I reading this correctly,  
 10 that heroin use over the period that was  
 11 studied in the -- in this NEJM article also  
 12 increased upon nonmedical users of  
 13 stimulants?

14 A. Yes, you're reading it  
 15 correctly.

16 Q. And what are examples of  
 17 stimulants?

18 A. Stimulants -- nicotine is a  
 19 stimulant. Methamphetamine is a stimulant.  
 20 Cocaine is a stimulant.

21 Q. And during the same time  
 22 period, heroin use also increased among users  
 23 of tranquilizers, sedatives, cocaine,  
 24 marijuana and alcohol, correct?

25 A. Yes.

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1 Q. Okay. And the next page, 158,  
 2 if you look at this first full paragraph, the  
 3 first sentence, the authors conclude that, "A  
 4 key factor underlying the recent increases in  
 5 rates of heroin use and overdose may be the  
 6 low cost and high purity of heroin."

7 Do you see that?

8 A. I do.

9 Q. And so am I reading that  
 10 correctly that the finding is that for --  
 11 when some persons who abuse prescription  
 12 opioids then subsequently initiate heroin  
 13 use, the cost and availability of heroin on  
 14 the street are primary factors in that  
 15 process?

16 A. To me that statement needs to  
 17 be put in the larger context of increased  
 18 exposure to heroin through a medical  
 19 prescription and subsequent development of  
 20 opioid addiction to medical heroin --  
 21 medical opioids, that then put all of those  
 22 individuals at increased risk to progress to  
 23 heroin use.

24 So I think that that statement,  
 25 as I read their intention, is that in the

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1 broader context of the Tsunami Effect and the  
 2 Gateway Effect, that then these price points  
 3 will impact what opioid people will use after  
 4 they've already become addicted.

5 Q. Do you have any basis to  
 6 disagree with the statement that when some  
 7 persons who abuse prescription opioids  
 8 initiate heroin use, it is cost and  
 9 availability of heroin that are primary  
 10 factors in this process, that specific  
 11 conclusion?

12 A. Where is that statement? Is  
 13 that something else you're reading, or is  
 14 that just your summary of --

15 Q. It is right at the bottom of  
 16 that same page you're looking at.

17 A. Okay.

18 Q. And it says, "Multiple studies  
 19 have examined why some persons who abuse" --  
 20 "multiple studies that have examined why some  
 21 persons who abuse prescription opioids  
 22 initiate heroin use indicate that the cost  
 23 and availability of heroin were primary  
 24 factors in this process."

25 Do you see that sentence?

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1 A. Uh-huh.  
 2 Q. Do you have any basis to  
 3 disagree with those studies or that  
 4 conclusion?  
 5 A. I don't, except that I would  
 6 add that the appetite for opioids generally  
 7 in the population began with increased  
 8 exposure to opioids through medical  
 9 prescribing.

10 Q. Okay.

11 A. And that was more of a factor  
 12 than later price points. That's my opinion.

13 Q. Well, if you look up one  
 14 paragraph above that, it's above the heading  
 15 "Break" on page 158, the New England Journal  
 16 of Medicine concludes, and I'll read it, "In  
 17 the context of marked increases in the rate  
 18 of heroin use, it is important to note that  
 19 only a small percentage of nonmedical users  
 20 of prescription opioids initiate heroin use."

21 Do you see that?

22 A. Uh-huh.

23 Q. And they go on to cite the  
 24 Muhuri study that we discussed that found a  
 25 rate of 3.6 percent of nonmedical

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1 prescription opioid users that then turn to  
 2 heroin use.  
 3 Do you see that?  
 4 A. Uh-huh.  
 5 Q. And they also cite the Jones  
 6 study, which has a similarly low number,  
 7 4.2 percent, of persons who had used  
 8 prescription opioids nonmedically then turn  
 9 to heroin use.

10 Do you see that?

11 A. (No response.)

12 Q. And do you have any basis to  
 13 disagree with those data?

14 A. I'm not disagreeing with those  
 15 data, but I think it would be important to  
 16 look at actual numbers, not just percentages,  
 17 because when looking at actual numbers of  
 18 people who are using opioids nonmedically who  
 19 progress to heroin use, it gets to be very  
 20 high numbers.

21 Q. Okay. And Compton talks about  
 22 the aggregate big picture. So at the very  
 23 bottom of that same paragraph, the NEJM  
 24 article states, "Yet taken in total, the  
 25 available data suggests that nonmedical

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1      prescription opioid use is neither necessary  
 2      nor sufficient for the initiation of heroin  
 3      use and that other factors are contributing  
 4      to the increase in the rate of heroin use and  
 5      related mortality."

6                Do you agree with that  
 7      statement?

8                MR. ARBITBLIT: Object to form.

9                THE WITNESS: I would say that  
 10         I agree that it's neither necessary  
        nor sufficient, but it has been a huge  
        factor in the last two decades, three  
        decades, among individuals who use  
        heroin as evidenced by survey studies  
        showing that 80 percent of people who  
        use heroin began with a prescription  
        opioid.

18        QUESTIONS BY MR. TSAI:

19        Q.        And they use that nonmedically,  
 20      that figure?

21        MR. ARBITBLIT: Object to form.

22        QUESTIONS BY MR. TSAI:

23        Q.        Correct?

24        A.        Let me look at that.

25        My reading of that article is

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1      that it wasn't just individuals who had used  
 2      prescription opioids nonmedically. It was --  
 3      also included individuals who had received an  
 4      opioid through a medical prescription.

5                Q.        And if that was the case, that  
 6      is what you would have stated in your report,  
 7      if it encompassed both medical use,  
        appropriate medical use, and nonmedical use?

9                MR. ARBITBLIT: Object to form.

10        THE WITNESS: Give me a moment.  
 11        Let me find it in my report.

12        MR. TSAI: Can we go off the  
 13      record while the witness is looking  
 14      through?

15        VIDEOGRAPHER: Okay. Should  
 16      we?

17        MR. ARBITBLIT: Yes.

18        VIDEOGRAPHER: We're now going  
 19      off the record, and the time is  
 20      10:47 a.m.

21        (Off the record at 10:47 a.m.)

22        VIDEOGRAPHER: We are now going  
 23      back on the record, and the time is  
 24      10:49 a.m.

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1      QUESTIONS BY MR. TSAI:

2        Q.        So we talked about necessary  
 3      and sufficient in the Compton article.  
 4        So am I right that not  
 5      sufficient -- "nonmedical prescription opioid  
 6      use is not sufficient for the initiation of  
 7      heroin use."

8        What that means is that not  
 9      every person who engages in nonmedical  
 10     prescription opioid use turns or -- turns to  
 11     or becomes addicted to illegal heroin.

12        That's what "not sufficient"  
 13      means, agree?

14        A.        Yes, I agree.

15        Q.        And "not necessary," in this  
 16      context of this finding, means that  
 17      individuals who become -- who develop an  
 18      addiction to or overdose from illegal heroin  
 19      can and are driven to heroin due to reasons  
 20      that are different from prior use of  
 21      prescription opioids, agree?

22        MR. ARBITBLIT: Object to form.

23        THE WITNESS: Let me read the  
 24      last part of this.

25        When you say "are driven to

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1      heroin use due to reasons that are  
 2      different from prior use of  
 3      prescription opioids," can you explain  
 4      that, what you mean by that?

5      QUESTIONS BY MR. TSAI:

6        Q.        Sure.

7        The Compton article expressly  
 8      refers to other factors that are contributing  
 9      to the increase in the rate of heroin use and  
 10     related mortality.

11        So do you acknowledge and agree  
 12      that there are factors other than  
 13      prescription opioid use that are contributing  
 14      to the Gateway Effect increase in the rate of  
 15      heroin use and related mortality?

16        A.        Yes, I do.

17        Can I go back to something  
 18      earlier? Just the -- I did find the article  
 19      in my report, the Cicero article.

20        Q.        Actually, I think the way this  
 21      works is Don can do redirect at the end.

22        A.        Okay.

23        Q.        And I'm sure he'll pick up on  
 24      that.

25        So let me ask again: They use

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1 the term "it is not necessary."

2 So "not necessary" means that

3 individuals who are addicted to or overdose

4 from illegal heroin can develop that

5 condition, that outcome, because of reasons

6 that are different from prior use of

7 prescription opioids?

8 A. I guess I'm struggling a little

9 bit with your phrasing of "reasons that are

10 different," and I know you tried to define

11 that, but I think it's -- when I hear reasons

12 that are different, I want to make sure that

13 I'm, you know, answering precisely.

14 It seems like you're implying

15 that somehow those people are different or

16 their lives are different or their -- there's

17 something fundamentally different about them,

18 and I wouldn't agree with that.

19 I would say that, you know, the

20 disease of addiction and how it progresses in

21 a human being is really pretty similar across

22 the board. There aren't really shocking

23 differences independent of what the substance

24 is.

25 Q. Well, you agree that the

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1 outcome of heroin use, taking that as the end

2 point, prescription opioid use is not

3 necessary for that to occur?

4 A. Yes, I agree with that.

5 Q. Okay. And you agree that

6 there's not a straight line, one-to-one

7 relationship between individuals who are

8 prescribed opioid medications on the one hand

9 and individuals who are addicted to illegal

10 street heroin and fentanyl?

11 A. I would disagree with that.

12 Q. Isn't that what the Compton

13 article says, though?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: No. So what you

16 said is would you "agree that there is

17 not a straight line, one-to-one

18 relationship between individuals who

19 are prescribed opioid medications on

20 the one hand and individuals who are

21 addicted to illegal street heroin and

22 fentanyl."

23 And I would say that there is a

24 straight line between individuals who

25 are prescribed opioid medications and

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1 those who get addicted to illegal

2 street heroin and fentanyl.

3 It's not the only path, but

4 there is a very clear path between

5 those things.

6 QUESTIONS BY MR. TSAI:

7 Q. Okay. Well, could you turn

8 back to the Edlund article? And page 7 of

9 this. So it's the last full paragraph on

10 page 7 of the Edlund article, I believe.

11 And the second sentence says,

12 "In particular, pathways to OUDs may involve

13 several steps, moving from low dose/acute

14 dose to high dose/chronic use."

15 Do you see that?

16 A. Yes, I do.

17 Q. Do you agree that there, an

18 individual, who ultimately develops an opioid

19 use disorder with respect to illegal heroin,

20 takes many steps to get to that outcome?

21 MR. ARBITBLIT: Object to form.

22 THE WITNESS: What I would say

23 to that is that one of the most

24 salient findings in the Edlund article

25 is that the biggest predictor of

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1 developing an opioid use disorder was

2 dose and duration of the opioid far

3 exceeding risks related to personal

4 past history of substance use or

5 co-occurring mental illness.

6 So that to me is a powerful

7 finding because it says that although

8 people are different and they have

9 different life factors, that what

10 really predicted progression -- what

11 really predicts progression among

12 patients treated for chronic pain with

13 an opioid is how high their dose is

14 and how long they're prescribed it.

15 QUESTIONS BY MR. TSAI:

16 Q. Well, if you could turn to the

17 next page of Edlund, page 8.

18 So the second full sentence at

19 the top of the page, it states, "Evidence to

20 date suggests this is largely a

21 self-selection process by the patients where

22 most patients started on opioid therapy

23 choose not to continue on to chronic use."

24 Do you see that?

25 A. Uh-huh.

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1 Q. So just taking a step back: Do  
 2 you agree that individuals who are taking  
 3 prescription opioid medications are still  
 4 capable of making choices, including, as  
 5 Edlund observes, choosing not to continue on  
 6 to chronic use?

7 MR. ARBITBLIT: Object to form.

8 THE WITNESS: I think the use  
 9 of the term in this sentence  
 10 "self-selection" is a poor choice of  
 11 words because people who develop the  
 12 disease of addiction do lose  
 13 volitional control over their choices,  
 14 such that they do actually, in many  
 15 instances, lack capacity to choose to  
 16 continue or not continue with their  
 17 opioid.

18 QUESTIONS BY MR. TSAI:

19 Q. So do you disagree with the  
 20 authors of this study that you cite in using  
 21 the word "choose"?

22 MR. ARBITBLIT: Object to form.

23 THE WITNESS: No.

24 I agree with the authors of  
 25 this study, but if you want to focus

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1 on this one particular sentence, I  
 2 disagree with the language that they  
 3 have used in this sentence to describe  
 4 the process of progressing to  
 5 addictive use in the context of  
 6 receiving an opioid prescription from  
 7 a doctor.

8 QUESTIONS BY MR. TSAI:

9 Q. Addiction is a disease that  
 10 takes time to manifest and develop; do you  
 11 agree?

12 A. In most cases, yes. Not in  
 13 all, but in most cases.

14 Q. And can we agree that not every  
 15 person who takes a prescription opioid  
 16 medication immediately becomes addicted?

17 A. Yes, I agree with that.

18 Q. And we can agree that not every  
 19 person who takes a prescription opioid  
 20 medication inevitably becomes addicted?

21 A. It would really depend on which  
 22 definition of addiction you're using.

23 If you're using the DSM-IV  
 24 definition that includes physiologic  
 25 dependence, then I think the vast majority

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1 will inevitably become physiologic dependent  
 2 on that opioid, and using the old  
 3 nomenclature, they would meet criteria for  
 4 opioid addiction.

5 Q. Is it your opinion that if any  
 6 person develops a dependence on a  
 7 prescription opioid, then it's game over;  
 8 they're dependent for the rest of their  
 9 lives?

10 MR. ARBITBLIT: Object to form.

11 THE WITNESS: Well, I would  
 12 hate to say "game over," you know, in  
 13 any clinical context. And they are  
 14 dependent until they get off and  
 15 recover their original state, assuming  
 16 that they're able to do that. In many  
 17 cases, they're not able to do that.

18 QUESTIONS BY MR. TSAI:

19 Q. So to the extent an individual  
 20 using prescription opioids starts on a path  
 21 to tolerance, dependence or opioid usage  
 22 disorder, that can be reversed; you agree?

23 A. Yes, I do.

24 MR. TSAI: Okay. Let's take a  
 25 break.

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1 MR. ARBITBLIT: Okay. Well,  
 2 before we take a break, under Rule 106  
 3 which says that "if a party introduces  
 4 all or a part of a writing or recorded  
 5 statement, an adverse party may  
 6 require the introduction at that time  
 7 of any other part or any other writing  
 8 or recorded statement that in fairness  
 9 ought to be considered at the same  
 10 time."

11 I'm not aware of anything in  
 12 the protocol that would overrule the  
 13 federal rules, and I haven't been  
 14 advised of such at this deposition.

15 And from the Compton study that  
 16 counsel introduced at page 155, I will  
 17 introduce the following under  
 18 Rule 106. "Heroin is  
 19 pharmacologically similar to  
 20 prescription opioids. All these drugs  
 21 produce their action through  
 22 endogenous opioid systems that  
 23 regulate a wide range of functions  
 24 through three major types of G protein  
 25 coupled receptors, mu, delta and

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1           kappa, with particularly potent  
 2           agonist activity at the mu receptor  
 3           and weak activity at the delta and  
 4           kappa receptors."

5           At page 156, just above the  
 6           sentence that counsel read, the  
 7           following appears, "Several  
 8           prescription opioids such as  
 9           hydromorphone, fentanyl, morphine and  
 10          oxycodone have a potential for abuse  
 11          that is similar to and in some cases  
 12          even higher than the potential for  
 13          abuse with heroin."

14          At page 157 of the same  
 15          article, "A recent study with data  
 16          through 2013 showed that prescription  
 17          opioid abuse or dependence was  
 18          associated with the likelihood of  
 19          heroin abuse or dependence that was 40  
 20          times as great as the likelihood with  
 21          no prescription opioid abuse or  
 22          dependence even after accounting for  
 23          sociodemographic, geographic and other  
 24          substance abuse or dependence  
 25          characteristics.

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1           "These studies suggest a clear  
 2           link between nonmedical use of  
 3           prescription opioids and heroin use,  
 4           especially among persons with  
 5           frequent, nonmedical use, or those  
 6           with prescription opioid abuse or  
 7           dependence."

8           And finally, at page 158, "Of  
 9           note, given the large number of  
 10          nonmedical users, even a small  
 11          percentage who initiate heroin use  
 12          translates into several hundred  
 13          thousand new heroin users."

14          We can take a break.

15          MR. TSAI: This is absolutely  
 16          abuse of process, and it -- I think  
 17          collectively we've been in dozens of  
 18          these. This has never occurred  
 19          before, Don.

20          Will you agree to give me a  
 21          minute-for-minute allocation?

22          MR. ARBITBLIT: Yes,  
 23          absolutely, and I would ask the court  
 24          reporter -- I offered that during the  
 25          break. The court reporter can add up

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1           whatever time I've used. You can have  
 2           minute-for-minute increase to your  
 3           time, but Rule 106 is not abuse, and I  
 4           object strongly to that  
 5           characterization.

6           MR. TSAI: Let's go off the  
 7           record.

8           MR. STAMPFL: I would also like  
 9           to say on behalf of Allergan  
 10          defendants that I think this is  
 11          improper, but plaintiffs have waived  
 12          any right to object to this practice  
 13          during the depositions of defendants'  
 14          experts. Thank you.

15          VIDEOGRAPHER: Okay. We are  
 16          now going off the record, and the time  
 17          is 11:02 a.m.

18          (Off the record at 11:02 a.m.)

19          VIDEOGRAPHER: We are now going  
 20          back on the record, and the time is  
 21          11:18 a.m.

22          QUESTIONS BY MR. TSAI:

23          Q. So you acknowledge in your  
 24          report that there are patients with moderate  
 25          to severe chronic pain and co-occurring

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1           mental health disorders: Depression,  
 2           anxiety, PTSD.

3           Do you recall that?

4          A. Yes.

5          Q. And co-occurring,

6          co-occurrence, means these individuals have  
 7          mental health disorders like depression or  
 8          anxiety or PTSD while also having the disease  
 9          of opioid use disorder?

10         A. Yes. Another way that --  
 11         because of the opioid epidemic, when we use  
 12         the term "co-occurrence," we're often also  
 13         using chronic pain as part of a co-occurring  
 14         addict -- disorder with the disease of  
 15         addiction.

16         Q. Have you done any analysis or  
 17         have any other basis to quantify the  
 18         percentage of people with opioid use disorder  
 19         in Cuyahoga and Summit Counties who have  
 20         co-occurring mental health disorders like  
 21         depression, anxiety, PTSD?

22         A. I haven't done that analysis  
 23         specific to Cuyahoga County. There are  
 24         others who have done that analysis in other  
 25         populations.

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1 Q. Have you done any analysis or  
 2 have any other basis to reliably rule out the  
 3 likelihood that individuals in Cuyahoga and  
 4 Summit Counties with opioid use disorder had  
 5 mental health disorders prior to opioid use  
 6 disorder?

7 MR. ARBITBLIT: Object to form.

8 THE WITNESS: No.

9 QUESTIONS BY MR. TSAI:

10 Q. If an individual who has a  
 11 co-occurring mental health disorder, along  
 12 with an opioid use disorder, along with  
 13 chronic pain, commits suicide, let's say, how  
 14 do you untangle and determine whether the  
 15 suicide was due to the mental health  
 16 disorder, the opioid use disorder or the  
 17 pain?

18 MR. ARBITBLIT: Object to form.

19 Incomplete hypothetical.

20 There's a question pending.

21 THE WITNESS: Yes, I'm sorry.

22 I'm thinking.

23 MR. ARBITBLIT: Okay. Sorry.

24 THE WITNESS: No, that's okay.

25 So suicide and opioid use

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1 disorder and chronic pain have a  
 2 complex relationship in which each one  
 3 can exacerbate -- each condition can  
 4 exacerbate the other.

5 And the individual  
 6 circumstances of the death would -- I  
 7 would need the data on the individual  
 8 circumstances of the death to be able  
 9 to determine specifically -- well, to  
 10 be able to try to assess to the best  
 11 of my ability what was the reason for  
 12 the death or what were the  
 13 circumstances leading up to that  
 14 death.

15 But -- I guess I'll just leave  
 16 it at that time.

17 QUESTIONS BY MR. TSAI:

18 Q. And have you reviewed any  
 19 information about, as you call it, the  
 20 individual circumstances of any such deaths,  
 21 the reason -- the context with respect to any  
 22 opioid-related deaths in Cuyahoga and Summit  
 23 Counties?

24 A. Well, I have reviewed the  
 25 prescribing rates of opioids based off CDC

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1 data in those counties, and I know that rates  
 2 of prescribing are -- in a given county or in  
 3 a given geographic region correlate with risk  
 4 of opioid use disorder and opioid-related  
 5 deaths in that region -- in that region and  
 6 are likely causative.

7 So in that sense I have  
 8 reviewed some data.

9 MR. TSAI: I'll move to strike  
 10 that answer.

11 QUESTIONS BY MR. TSAI:

12 Q. The aggregate prescribing rates  
 13 of opioids, does that give you any  
 14 information about the individual  
 15 circumstances, to use your term, of any  
 16 opioid-related deaths?

17 MR. ARBITBLIT: Object to form.

18 THE WITNESS: I do believe that  
 19 the aggregate prescribing in that  
 20 county is a risk factor for  
 21 individuals living in that county as  
 22 to whether they will die by overdose  
 23 death.

24 QUESTIONS BY MR. TSAI:

25 Q. And do you agree that the

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1 co-occurrence or the preexisting existence of  
 2 mental health disorders such as depression,  
 3 anxiety, PTSD, trauma, is also a risk factor  
 4 for individuals as to whether they will die  
 5 by opioid-related death?

6 A. It's not as important a risk  
 7 factor as access to opioids as described by  
 8 the Edlund study and decided in my report  
 9 which finds that dose and duration of opioids  
 10 is the most important risk factor and more  
 11 important than individual factors such as  
 12 co-occurring mental illness.

13 Q. You agree that the Edlund study  
 14 described that individuals with a preexisting  
 15 mental health disorder had higher rates of  
 16 opioid use disorder than individuals with no  
 17 mental health disorder?

18 Are you familiar with that --  
 19 you agree with that --

20 MR. ARBITBLIT: Objection.

21 QUESTIONS BY MR. TSAI:

22 Q. -- trend?

23 MR. ARBITBLIT: Object to form.

24 THE WITNESS: Yes.

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1       QUESTIONS BY MR. TSAI:

2           Q.     Okay. And similarly,  
3     individuals with two preexisting mental  
4     health disorders have higher rates of opioid  
5     use disorder than individuals with one mental  
6     health disorder; do you agree?

7           A.     I haven't seen data on two  
8     versus one mental health disorder, so I --

9           Q.     You didn't review that in the  
10    Edlund study?

11          A.     Was it in the Edlund study?

12          Q.     I believe so, but I'll move on.

13          A.     Uh-huh.

14          Q.     Have you conducted any  
15    analysis, quantitative analysis, or have any  
16    other basis to reliably rule out that the  
17    co-occurrence of the preexisting presence of  
18    depression, anxiety, trauma or other mental  
19    illness was an important contributing factor  
20    leading to opioid addiction and mortality in  
21    Cuyahoga and Summit Counties?

22          MR. ARBITBLIT: Object to form.

23          THE WITNESS: I feel like I  
24    already answered this question.

25

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1       QUESTIONS BY MR. TSAI:

2           Q.     So it should be quite easy for  
3     you to answer it.

4                   Have you?

5           A.     I think I did already answer  
6     it, just in terms of, on what basis.

7           Q.     So am I right that your answer  
8     to this question is the aggregate prescribing  
9     rates, this is what you would point to?

10          MR. ARBITBLIT: Object to form.

11          QUESTIONS BY MR. TSAI:

12          Q.     What does the aggregate  
13    prescribing rates have to do with the  
14    co-occurrence of mental illness?

15          A.     I'm trying to figure out the  
16    question.

17                   Could you rephrase the  
18    question?

19          Q.     Do you have any basis to  
20    reliably rule out that the preexisting  
21    presence or the co-occurrence of mental  
22    illness among individuals in Cuyahoga and  
23    Summit County who had opioid use disorder,  
24    opioid use overdose, do you have -- have you  
25    done any analysis, do you have any basis to

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1       rule out that mental illness was an important  
2     contributing factor to those outcomes?

3           MR. ARBITBLIT: Object to form.

4          THE WITNESS: So mental illness  
5     increases risk of addiction. Mental  
6     illness increases risk of having  
7     chronic pain. But the risk conferred  
8     by mental illness is not as great as  
9     the risk conferred by access to those  
10    drugs.

11          QUESTIONS BY MR. TSAI:

12          Q.     And are you willing to offer  
13    the opinion to conclusively say that no  
14    individuals in Cuyahoga and Summit County  
15    with opioid use disorder or overdose had a  
16    mental illness co-occurring or preexisting?

17          MR. ARBITBLIT: Object to form.

18          QUESTIONS BY MR. TSAI:

19          Q.     Would that be speculation on  
20    your part, or do you have a basis to make  
21    that opinion?

22          MR. ARBITBLIT: Object to form.

23          Misstates the testimony.

24          THE WITNESS: Could you  
25    rephrase the question, because you

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1       used a double negative, so it's a  
2     little hard for me to track? I'm  
3     sorry.

4          QUESTIONS BY MR. TSAI:

5          Q.     Well, is it your opinion that  
6     none of the individuals in Cuyahoga and  
7     Summit County who had opioid use disorder or  
8     an opioid use-related overdose had  
9     significant preexisting or co-occurring  
10    mental illness?

11          A.     That is not my opinion.

12          Q.     Okay. Do you agree that  
13    suicide rates are elevated, just isolating  
14    individuals with chronic pain, especially  
15    when there's a sense of hopelessness about  
16    treating that pain?

17          MR. ARBITBLIT: Object to form.

18          THE WITNESS: Sorry. I can't  
19    speak to the sense of hopelessness  
20    part, linking it to chronic pain. It  
21    is true that when people experience a  
22    sense of hopelessness, that can  
23    sometimes lead them to consider ending  
24    their lives. And it makes sense to me  
25    that individuals with chronic pain

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1       would have elevated suicide rates, but  
 2       I think the interplay between opioid  
 3       therapy for pain, hopelessness,  
 4       depression and suicide are complex  
 5       because opioids themselves can  
 6       contribute to depression and  
 7       suicidality.

8           So it's very hard to tease  
 9       apart what part of that is due to a  
 10      separate depressive disorder and what  
 11      part of that may actually be an  
 12      opioid-induced depressive disorder.

13 QUESTIONS BY MR. TSAI:

14       Q.     And what would you need to  
 15      review and analyze to be able to tease apart  
 16      those complex layers of confounding factors?

17       MR. ARBITBLIT: Object to form.

18       THE WITNESS: Those are hard to  
 19      tease apart, even in clinical care.

20       Typically what we use is some  
 21      kind of lifetime timeline to try to  
 22      look at when the mood disorder began  
 23      and when the opioids were started, but  
 24      even that is not necessarily  
 25      sufficient since opioids can worsen

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1       mood.  
 2       QUESTIONS BY MR. TSAI:  
 3       Q.     And we're talking about  
 4       co-occurring mental illness. Let's talk  
 5       about past history of substance use disorder.  
 6           Do you agree that past history  
 7       of substance use disorder is a  
 8       well-established risk factor for opioid use  
 9       disorder?

10      A.     Yes.

11      Q.     And let me just give an  
 12      example.

13       Edlund found that about half of  
 14      opioid overdose deaths involved another drug,  
 15      most commonly benzodiazepines.

16           Do you agree with that  
 17      observation?

18       MR. ARBITBLIT: Object to form.

19       THE WITNESS: I agree that a  
 20      large percentage of opioid overdose  
 21      deaths involve another drug, commonly  
 22      a sedative like a benzodiazepine.

23 QUESTIONS BY MR. TSAI:

24       Q.     And can you give some examples  
 25      of benzodiazepines?

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1       A.     Sure: Valium, Klonopin, Xanax,  
 2      Ativan, Librium.

3       Q.     And you talk about a large  
 4      percentage of opioid-related overdoses  
 5      involve an individual that, to put it  
 6      bluntly, has another addictive substance in  
 7      their system.

8       What do you mean by a large  
 9      percentage? Can you be more specific?

10      A.     Two-thirds of deaths involving  
 11      a benzodiazepine also involve an opioid  
 12      prescription.

13      Q.     And if you could turn to your  
 14      book, "Drug Dealer, MD," and page 146, the  
 15      internal page number of your book, and the  
 16      Bates number for that ends in 5680.

17      A.     Uh-huh.

18      Q.     It's the first full paragraph.  
 19      It says, "Today, doctors' prescription for  
 20      benzodiazepines continue to rise and are a  
 21      major culprit in the epidemic of prescription  
 22      overdose deaths plaguing this country.  
 23      Nonetheless, benzodiazepines are relatively  
 24      ignored in the national discussion on rising  
 25      rates of addiction."

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1       Is that still your belief?

2      A.     Yes.

3      Q.     And have you done any work or  
 4      analysis to quantify to what extent  
 5      benzodiazepines are, as you say, a major  
 6      culprit in the epidemic of prescription  
 7      overdose deaths plaguing this country?

8      A.     So I published an article in  
 9      the New England Journal of Medicine talking  
 10     about the benzodiazepine problem. The  
 11     article was not based on my own analysis, but  
 12     was a review of published literature and some  
 13     summative interpretations of how to  
 14     intervene.

15           And based on other  
 16     publications, we found a seven-time increased  
 17     mortality involved benzodiazepines between  
 18     late 1990s and 2016, two-thirds of which also  
 19     involved an opioid.

20      Q.     And did you, in connection with  
 21      this article, dig into or quantify whether  
 22      the benzodiazepine use occurred before or  
 23      after the prescription opioid use?

24      A.     No.

25      Q.     So in your report on page 89,

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1 you say, "Economic downturn and the E-flux of  
 2 manufacturing jobs in towns across America in  
 3 the last 30 years have contributed to  
 4 so-called deaths of despair, early mortality  
 5 in middle-aged, non-Hispanic whites due  
 6 primarily to drug overdose."

7 Do you remember that passage?

8 A. What page?

9 Q. I believe it's page 89 of your  
 10 report, Exhibit 1, subsection B, and you cite  
 11 to the Case, Deaton study.

12 Do you recall that?

13 A. Yes.

14 MR. TSAI: So can we get

15 Tab 18?

16 A. Oh, yeah. I found it.

17 (Lembke Exhibit 8 marked for  
 18 identification.)

19 QUESTIONS BY MR. TSAI:

20 Q. Okay. So if you could turn  
 21 to -- the first page of the Case, Deaton  
 22 article, this has a broad conclusion that  
 23 "from 1999 to 2013, there was an increase in  
 24 mortality among middle-aged, white,  
 25 non-Hispanic Americans from all causes."

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1 Is that right?

2 A. That's correct.

3 Q. And in the introduction, the  
 4 bold introductory section, this Case, Deaton  
 5 study concluded that "these increased  
 6 mortality was due to various factors,  
 7 including drug and alcohol poisonings,  
 8 suicide, chronic liver disease and  
 9 cirrhosis."

10 Is that right?

11 A. Yes.

12 Q. And second to the last -- just  
 13 to be clear, do opioids cause deterioration  
 14 or chronic liver disease or cirrhosis?

15 A. Not typically.

16 Q. Okay. And is it fair to say  
 17 that those drivers of the increased mortality  
 18 noted in the study were likely due to alcohol  
 19 use disorder or alcoholism colloquially?

20 A. Yes.

21 Q. Okay. And in your report, you  
 22 acknowledge and agree that, quote/unquote,  
 23 "economic disadvantage is a contributing  
 24 factor to opioid-related mortality risk."

25 Is that correct?

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1 A. I would agree that it is one  
 2 factor, but I also cited the Ruhm study,  
 3 arguing that economic disadvantage  
 4 contributes only 10 to 20 percent of  
 5 mortality risk attributable to opioids,  
 6 whereas the larger share of risk is due to  
 7 the supply of opioids in a given geographic  
 8 region.

9 Q. Okay. And have you conducted  
 10 any quantitative analysis of your own to  
 11 quantify the specific contribution of  
 12 economic disadvantage to opioid-related  
 13 mortality risk?

14 A. No.

15 Q. Do you have a model or an  
 16 analytical framework to untangle any costs  
 17 related to any such preexisting social and  
 18 economic problems versus any conduct by any  
 19 defendant with respect to Cuyahoga and Summit  
 20 Counties?

21 MR. ARBITBLIT: Object to form.

22 THE WITNESS: I think that the  
 23 Ruhm study could be used to inform a  
 24 model with respect to the risk  
 25 incurred by the supply of opioids

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1 versus economic disadvantage.

2 QUESTIONS BY MR. TSAI:

3 Q. Have you in this case yourself  
 4 done any work to rule out the likelihood that  
 5 social and economic problems preexisting in  
 6 the counties were an important contributing  
 7 factor to observe opioid use disorder and  
 8 mortality?

9 MR. ARBITBLIT: Object to form.

10 THE WITNESS: I have stated in  
 11 my report that economic factors were a  
 12 factor, but not the most important  
 13 factor.

14 The most important factor is  
 15 the supply of opioids in that county.  
 16 That is my opinion.

17 QUESTIONS BY MR. TSAI:

18 Q. And your opinion regarding the  
 19 relative degree of contribution of social and  
 20 economic problems, economic disadvantage,  
 21 versus any conduct by the defendants, is that  
 22 based on grappling with any county-specific  
 23 data, or is it only based on the Ruhm study  
 24 that you cited?

25 MR. ARBITBLIT: Object to form.

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1                   THE WITNESS: It's based on my  
 2 reading of the literature, not just  
 3 this particular study, but also other  
 4 studies showing that the amount of  
 5 opioid prescribing in a given  
 6 geographic region is the biggest  
 7 predictor of opioid use disorder and  
 8 opioid overdose in that region.

9                   MR. TSAI: Okay. Can we do tab  
 10 27?

11                   (Lembke Exhibit 9 marked for  
 12 identification.)

13 QUESTIONS BY MR. TSAI:

14                   Q. So I would like to dig down  
 15 into the actual ground floor circumstances of  
 16 how folks get prescribed opioid medications.

17                   So do you recall that last year  
 18 you gave a live interview on KQED with  
 19 Michael Krasny for a program entitled  
 20 "Medical Community Divided on Medicare's  
 21 Policy to Shorten High-Dose Opioid  
 22 Prescriptions"?

23                   A. Yes, I do.

24                   Q. Okay. And the exhibit that  
 25 we've just put in front of you, does this

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1 appear to be a true and correct transcript of  
 2 that interview that you participated in?  
 3                   A. Yes, it does.  
 4                   Q. Okay. And if you turn to  
 5 page 8, they may have misspelled your name,  
 6 but the Anna Lembke referred to, that's you?

7                   A. Which page?

8                   Q. It's page 8 of this exhibit.

9                   A. Yes.

10                  Q. Okay. So if you could turn to  
 11 page 22 of the exhibit, and I'll start with  
 12 line 2 of that page. I'll just read it.

13                  You stated --

14                  A. I'm sorry.

15                  Q. Oh, sure.

16                  A. I have two sets of page numbers  
 17 here. Is this page 7, parentheses 22 to 25?

18                  Q. That's correct.

19                  A. Okay.

20                  Q. And it's split up into  
 21 quadrants. So it's the left-hand quadrant,  
 22 page 22.

23                  A. Yeah.

24                  Q. And you stated, "While it's a  
 25 very complicated connection that I do address

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1 in my book, it's hard to kind of put it into  
 2 a sound bite, but in general, you know,  
 3 people who are suffering from poverty,  
 4 unemployment, low education, are also people  
 5 who are known to be at higher risk for  
 6 addiction.

7                    It's also true that this is a  
 8 population that has turned towards disability  
 9 payments as a way to make ends meet, and in  
 10 order to, you know, justify the sick role and  
 11 get disability payments. Many of these  
 12 individuals have been forced to take certain  
 13 type of medications because taking a  
 14 medication can legitimize the sick role. So  
 15 it's a complex web."

16                  Do you see that?

17                  A. Yes, I do.

18                  Q. What is "justifying the sick  
 19 role"? What does that mean?

20                  A. Well, that's a term that goes  
 21 back to Talcott Parsons, who identified  
 22 social roles that people adopt, and anybody  
 23 who participates in the health care system  
 24 and views themselves as a, quote/unquote,  
 25 patient is someone who has adopted the sick

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1 role.

2                  Q. Okay. In your opinion -- is it  
 3 still your opinion that certain individuals  
 4 who have turned to disability payments are  
 5 being forced to take certain types of  
 6 medications to justify the sick role?

7                  A. So this is part of -- this is  
 8 an excerpt from, as I state here, a much more  
 9 complicated issue that I address more  
 10 thoroughly in my book regarding how  
 11 disability can sometimes consciously or  
 12 otherwise encourage people living in poverty  
 13 to adopt the sick role as a way to get  
 14 disability payments.

15                  And in order to legitimize the  
 16 sick role, they have to participate in that  
 17 health care system, and in the '90s and early  
 18 aughts and through today, it turns out

19 participating in the health care system as a  
 20 pain patient was actually dangerous because  
 21 that -- the risk of being exposed  
 22 unnecessarily to opioids was and continues to  
 23 be very high, and exposure to opioids is one  
 24 of the major risk factors for addiction.

25                  Q. So you use the term "forced to

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1 take certain types of medications." Who in  
 2 your opinion is forcing these individuals to  
 3 take opioid medications to justify what  
 4 you've called the sick role?

5 MR. ARBITBLIT: Object to form.

6 QUESTIONS BY MR. TSAI:

7 Q. How does that mechanism work?

8 A. The individuals are being  
 9 forced by economic circumstance.

10 Q. And this phenomenon of being  
 11 forced by their individual economic  
 12 circumstance to take certain medications to  
 13 justify the sick role, have you reviewed any  
 14 data specific to Cuyahoga or Summit Counties  
 15 to determine whether that phenomenon occurred  
 16 in the counties?

17 A. Nationally we've seen a huge  
 18 increase in the number of people going on to  
 19 disability for chronic pain conditions. For  
 20 example, Social Security Disability insurance  
 21 today, there are more than 8 million people  
 22 enrolled in Social Security Disability  
 23 insurance, primarily for chronic pain  
 24 conditions.

25 So I believe that I can

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1 extrapolate that to include Cuyahoga and  
 2 Summit Counties, that there are individuals  
 3 there who -- with chronic conditions who have  
 4 gone on disability.

5 Q. Have you done the exercise of  
 6 extrapolating specifically to Cuyahoga and  
 7 Summit Counties?

8 A. Do you mean a quantitative  
 9 analysis?

10 Q. Yes.

11 A. No.

12 Q. Is it your opinion that  
 13 defendants have any role in structuring or  
 14 implementing the Social Security Disability  
 15 network?

16 MR. ARBITBLIT: Object to form.

17 THE WITNESS: I think  
 18 defendants have had a major role in  
 19 the narrative around how chronic pain  
 20 should be treated for patients who are  
 21 participating in the health care  
 22 system. And as a result, patients  
 23 have been endangered because of being  
 24 exposed to dangerous -- the dangerous  
 25 substance that is opioids.

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1 QUESTIONS BY MR. TSAI:

2 Q. Though, that's kind of  
 3 confusing to me. The narrative is -- it's a  
 4 very broad term.

5 A. Uh-huh.

6 Q. Can you point to any specific  
 7 instance where any conduct by a defendant  
 8 caused an individual within the disability  
 9 payment network, for example, Social Security  
 10 Disability, to have been forced to take their  
 11 particular opioid medication?

12 MR. ARBITBLIT: Object to form.

13 THE WITNESS: So I think  
 14 defendants have been involved in the  
 15 change, the cultural change, in our  
 16 conceptualization of pain and have  
 17 created a climate in which doctors  
 18 have been forced to treat pain with  
 19 opioids, such that individuals who are  
 20 on disability and get care for their  
 21 chronic pain are at increased risk to  
 22 be exposed to opioids.

23 QUESTIONS BY MR. TSAI:

24 Q. So you talked about climate,  
 25 the culture and narrative.

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1 These are all pretty  
 2 qualitative, would you agree?

3 MR. ARBITBLIT: Object to form.  
 4 THE WITNESS: Yes.

5 QUESTIONS BY MR. TSAI:

6 Q. Can you point to a specific  
 7 instance, act, that fits the scenario that  
 8 you've outlined?

9 MR. ARBITBLIT: Object to form.  
 10 THE WITNESS: Yeah.

11 So in my report, I talk about  
 12 the Wisconsin Pain and Policy Study  
 13 Group, and I provide evidence that  
 14 the -- that industry funded the Pain &  
 15 Policy Study Group, defendants funded  
 16 the Pain & Policy Study Group, over a  
 17 period of many years.

18 And the Pain & Policy Study  
 19 Group, in turn, carried out programs  
 20 that benefitted the industry, not only  
 21 by increasing access to opioids and  
 22 limiting regulatory scrutiny {sic},  
 23 but also changing the culture around  
 24 pain treatment and identifying a model  
 25 in which doctors feared retribution if

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1       they didn't use opioids to treat pain.

2       QUESTIONS BY MR. TSAI:

3       Q.       Can you point to any instance  
4       where anyone providing funds had a role in  
5       the design and conduct of the specific study  
6       or program that you're referring to?

7       MR. ARBITBLIT: Object to form.

8           THE WITNESS: On October 9,  
9           2002, Joranson wrote to Mr. Kaiko, a  
10          Purdue representative, quote, "For the  
11          past several years, without your  
12          support, some of the progress reported  
13          below would not have been possible,"  
14          end quote.

15       QUESTIONS BY MR. TSAI:

16       Q.       And in your view is that  
17          designing and conducting the study?

18       MR. ARBITBLIT: Object to form.

19       THE WITNESS: It's not a study  
20          they're referring to. It's the model  
21          policy rolled out by the Pain & Policy  
22          Study Group, which had enormous  
23          influence in the way that pain was  
24          treated and is still treated today --

25

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1       QUESTIONS BY MR. TSAI:

2       Q.       So --

3       A.       -- including creating a culture  
4       and a climate in which physicians felt  
5       required to use opioids to treat pain, and  
6       that if they were not using opioids, they  
7       were undertreating pain.

8       Q.       Can you point to any instance  
9       where any person providing funding was  
10       involved in the preparation, review or  
11       approval of this model policy?

12       MR. ARBITBLIT: Object to form.

13       THE WITNESS: So there was a  
14          book that was published called  
15          "Responsible Opioid Prescribing,"  
16          which listed as its funders Purdue  
17          Pharma, Endo, Janssen and Cephalon.

18       And that book was widely  
19          promoted and disseminated by the Pain  
20          & Policy Study Group, and then  
21          subsequently by the Federation of  
22          State Medical Boards and contributed  
23          to this change in culture.

24       QUESTIONS BY MR. TSAI:

25       Q.       Okay. So it sounds like you're

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1       going back to funding, but I'm asking about  
2       the specific content authoring, editing.

3       MR. ARBITBLIT: Object to form.

4       QUESTIONS BY MR. TSAI:

5       Q.       Can you point to an example  
6       that shows that?

7       MR. ARBITBLIT: Object to form.

8       THE WITNESS: Can you repeat  
9       your question? I don't think I fully  
10       understand it.

11       QUESTIONS BY MR. TSAI:

12       Q.       So you've said that the  
13       promotion was by PROP, correct?

14       MR. ARBITBLIT: Object.

15       Misstates the record.

16       THE WITNESS: No.

17       QUESTIONS BY MR. TSAI:

18       Q.       It was widely disseminated --

19       MR. ARBITBLIT: PROP was not in  
20       the question. It was EESG, Counsel.

21       THE WITNESS: Pain & Policy  
22       Study Group.

23       QUESTIONS BY MR. TSAI:

24       Q.       Okay. That group. So I'm  
25       asking about the control, the authoring, the

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1       editing of any specific content or analysis.  
2           Other than funding, can you  
3       give me any example that supports your  
4       opinion about this culture or narrative or  
5       climate?

6       MR. ARBITBLIT: Object to form.  
7       THE WITNESS: The funding is  
8       really what made it possible for the  
9       Pain & Policy Study Group to roll out  
10       this new paradigm around pain  
11       treatment.

12       They're not the only group that  
13       collaborated with the opioid  
14       pharmaceutical industry in this  
15       endeavor.

16       Also the Joint Commission was  
17       involved in that process, and they  
18       actually received content that was  
19       created by Purdue Pharma. That was  
20       then disseminated to hospitals who  
21       were trying to make Joint Commission  
22       accreditation. They used videos  
23       produced by Purdue. They used  
24       documents created by Purdue in order  
25       to change the paradigm around opioid

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1 prescribing, including promoting  
 2 opioid -- including promoting pain as  
 3 the fifth vital sign.  
 4 There are also other examples  
 5 in my report where consultants for the  
 6 defendants were involved in research  
 7 studies that were also  
 8 misrepresentations of the evidence or  
 9 used the evidence in a way that  
 10 misrepresented the real science.

11 QUESTIONS BY MR. TSAI:

12 Q. And those are examples that  
 13 you've set forth in your report?

14 A. Yes.

15 (Lembke Exhibit 10 marked for  
 16 identification.)

17 QUESTIONS BY MR. TSAI:

18 Q. Okay. Hand you next in order.

19 So do you recall that you gave  
 20 a TEDx Talk in 2017?

21 A. Yes.

22 Q. And does the exhibit I've  
 23 handed you appear to be a true and correct  
 24 transcript of your TEDx Talk?

25 A. Yes.

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1 MR. ARBITBLIT: Counsel, it's  
 2 complete? Counsel, are you  
 3 representing that it's a complete  
 4 transcript or an excerpt?

5 MR. TSAI: This is a complete  
 6 transcript. I know you're a big fan  
 7 of completeness.

8 MR. ARBITBLIT: Yes, I am, and  
 9 I'm not apologizing for it, so if you  
 10 want to refrain from colloquy, please  
 11 do.

12 QUESTIONS BY MR. TSAI:

13 Q. Is the "Dr. Lembke" referred to  
 14 here you?

15 A. Yes.

16 Q. So if you could turn to page 3,  
 17 and I'll start with line 4, and I'll read it.

18 "But the truth is that big  
 19 pharma existed well before this public health  
 20 crisis. And frankly the term 'quack' dates  
 21 back to the 17th Century, so the question is:  
 22 Why this drug and why now? To really be able  
 23 to understand this problem, we have to  
 24 recognize that this current opioid epidemic  
 25 is a symptom of a faltering health care

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1 system and a culture that has demonized  
 2 pain."

3 Do you see that?

4 A. Yes, I do.

5 Q. And what do you mean when you  
 6 say "to really be able to understand this  
 7 problem, we have to recognize that this  
 8 current opioid epidemic is a symptom of a  
 9 faltering health care system and a culture  
 10 that has demonized pain"?

11 A. What I mean is that the  
 12 defendants have leveraged those problems in  
 13 the delivery of health care today in order to  
 14 meet their own agenda, which was a profit  
 15 agenda.

16 So there are other factors that  
 17 have contributed, but the primary factor is  
 18 the role of the defendants in this case, and  
 19 I would say that the defendants are  
 20 additionally to blame because of their  
 21 deliberate and for-profit misrepresentation  
 22 of the evidence, whereas health care  
 23 providers were unwitting accomplices.

24 Q. And presumably you would have  
 25 stated that in this talk, outlining the major

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1 contributing forces driving the opioid  
 2 epidemic?

3 MR. ARBITBLIT: Object to form.  
 4 THE WITNESS: I had ten minutes  
 5 in this TED Talk, and so I didn't  
 6 cover everything that I believe or  
 7 everything that's in my book.

8 QUESTIONS BY MR. TSAI:

9 Q. So because you had a limited  
 10 time, just like we do here, you had to  
 11 prioritize; is that right?

12 MR. ARBITBLIT: Object to form.  
 13 THE WITNESS: As I stated just  
 14 above there in line 3, "Big pharma  
 15 really is to blame."

16 QUESTIONS BY MR. TSAI:

17 Q. Well, you also state that, "In  
 18 order to understand what caused this  
 19 epidemic, we need to be aware of three  
 20 invisible forces inside of the health care  
 21 system that are driving this problem."

22 Do you see that?

23 A. Yes, I do.

24 MR. ARBITBLIT: Object to form.  
 25 Argumentative.

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1       QUESTIONS BY MR. TSAI:

2           Q.     Is that -- those are your  
3       words?

4           A.     Yes.

5           Q.     Okay. Is that still your  
6       opinion?

7           A.     Yes, but as I stated very  
8       clearly in my report, although there are  
9       other factors and other players in the opioid  
10      epidemic, the pharmaceutical opioid industry  
11      is the major driving factor and primarily  
12      responsible and basically took advantage of  
13      the other players as unwitting accomplices in  
14      their deliberate manipulation of the paradigm  
15      around pain treatment.

16          Q.     Well, let's see what you said.  
17           You enumerated the three forces  
18       that you say are driving this problem?  
19           Do you see that? So can we go  
20      through those?  
21           Is it your opinion still, as  
22       you stated in your talk in 2017, that the  
23       current opioid crisis is caused by, quote,  
24       "the industrialization of medicine or the  
25       Toyota-zation of medicine"?

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1           MR. ARBITBLIT: Object to form.  
2           Misstates the record.  
3           THE WITNESS: Yes, and I also  
4       mentioned that in my report, but  
5       again, importantly, the defendants  
6       basically took advantage of the  
7       fractured health care industry in  
8       order to misrepresent the evidence for  
9       their own gain.  
10       QUESTIONS BY MR. TSAI:  
11          Q.     Well, can you tell the jury  
12       when you coined the term "Toyota-zation of  
13       medicine," or "industrialization of  
14       medicine," what do you have in mind by that?  
15           What does that mean?  
16          A.     What I mean by that is the way  
17       in which doctors now no longer work in  
18       physician-owned practice. The majority of  
19       doctors now work for large, integrated health  
20       care centers, so they're essentially salaried  
21       employees, which means that they're required  
22       to practice medicine according to certain  
23       preordained protocols and algorithms.  
24           They have much less autonomy  
25       than they've ever had before. There's

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1       enormous pressure on them to make sure that  
2       patients are satisfied with their care, and  
3       all of that has -- there's also pressure on  
4       doctors to see patients more quickly, to get  
5       them in and out faster.  
6           Q.     All right. So --  
7           A.     And there's also pressures from  
8       the Joint Commission to meet certain quality  
9       measure standards.  
10           So the bottom line is that  
11      doctors today have much less autonomy than  
12      they had previously and are required to  
13      practice medicine in ways mandated by, for  
14      example, Joint Commission quality measures.  
15          Q.     So they mandate to practice  
16      medicine according to certain preordained  
17      protocols and algorithms?

18          A.     Yeah.

19          Q.     Who is responsible for  
20      formulating those protocols and algorithms?

21          A.     I believe that the defendants  
22      had a major and driving role in influencing  
23      those protocols in the treatment of pain.

24          Q.     Do others have a role in  
25      implementing or formulating the protocols and

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1       algorithms you refer to?  
2           When a doctor -- say in your  
3       example, a doctor says, "Here's this  
4       preordained algorithm that's forcing me to  
5       practice in a certain way," where is he or  
6       she hearing that from?

7           MR. ARBITBLIT: Object to form.

8       QUESTIONS BY MR. TSAI:

9          Q.     Where is it from?  
10        MR. ARBITBLIT: Object to form.  
11           THE WITNESS: They're hearing  
12       that from continuing medical education  
13       courses that, for example, I was  
14       mandated to attend in 2001 when  
15       legislation was passed in the state of  
16       California mandating every physician  
17       to attend a pain medicine course in  
18       order to maintain their license.

19           And at that course, I  
20      distinctly remember being taught many  
21      of the myths regarding opioid  
22      prescribing, information that's not  
23      based on science, about the benefits  
24      of the use of opioids and chronic pain  
25      and the low risk of addiction as long

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1 as that individual has pain being  
 2 prescribed opioids by a doctor. And  
 3 we know none of that is true. That's  
 4 just one of many examples, continuing  
 5 medical education courses.

6 Another important example is  
 7 the Joint Commission that accredits  
 8 hospitals. They have an enormous  
 9 influence on how we practice medicine  
 10 today. We know as physicians that we  
 11 have to meet Joint Commission  
 12 standards, and the Joint Commission  
 13 made assessing pain a quality measure  
 14 in 2001 using material obtained by  
 15 Purdue Pharma, that they then sold to  
 16 hospitals, so that hospitals could  
 17 meet Joint Commission requirements.

18 Doctors also get that  
 19 information from the literature that  
 20 they read, peer-reviewed articles, and  
 21 many of those articles were misused  
 22 essentially as promotional material  
 23 with authors that were either  
 24 consultants for pharma or with a study  
 25 that was supported by pharma.

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1 So those are the types of  
 2 things I'm talking about.

3 QUESTIONS BY MR. TSAI:

4 Q. What about hospital  
 5 administrators, do they have an important  
 6 role in ordaining and mandating protocols and  
 7 algorithms as you've referred to?

8 A. Hospital administrators have an  
 9 important role in that, but, again, any role  
 10 that they played, I believe, was as unwitting  
 11 accomplices in the deliberate  
 12 misrepresentation of the benefits of opioids  
 13 and their risks by the defendants.

14 Q. Third-party payers, health  
 15 insurance companies, they have an important  
 16 role in ordaining the mandates and the  
 17 protocols and the algorithms within the  
 18 industrialized medicine system that you  
 19 referred to?

20 A. Yes, they do.

21 Q. Okay. And when you say that,  
 22 you know, there's a doctor, he or she feels  
 23 enormous pressure to make -- satisfy his or  
 24 her patients, get them quickly out, having  
 25 industrial line, like an assembly line, who

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1 is that pressure coming from?  
 2 MR. ARBITBLIT: Object to form.  
 3 THE WITNESS: That pressure  
 4 comes from the patients themselves and  
 5 the desire of the doctor to do a good  
 6 job, and usually people who go into  
 7 medicine are people who want to have  
 8 quality relationships with their  
 9 patients and feel like they help their  
 10 patients. But there are also  
 11 institutional pressures on doctors to  
 12 have good doctor/patient satisfaction  
 13 surveys.

14 And there's also importantly  
 15 patients' expectations around what  
 16 they expect the doctor will provide to  
 17 them when they see that doctor.

18 And because of the defendants'  
 19 actions, patients came to expect that  
 20 when they had pain, they should get an  
 21 opioid from their doctor. And we do  
 22 know that there are data showing that  
 23 when patients' expectations are not  
 24 met, they're more likely to rate that  
 25 doctor poorly.

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1 So there was overall enormous  
 2 pressure on doctors and on the system  
 3 to prescribe opioids even for minor  
 4 and chronic pain conditions in the  
 5 absence of evidence because that  
 6 evidence was misrepresented to all of  
 7 these various parties by the  
 8 defendants.

9 QUESTIONS BY MR. TSAI:

10 Q. Have you done any analysis --  
 11 do you have any other basis to reliably rule  
 12 out the likelihood that there are these  
 13 pressures on prescribing doctors following  
 14 protocols and algorithms that came from  
 15 sources that had nothing to do with  
 16 defendants?

17 MR. ARBITBLIT: Object to form.  
 18 THE WITNESS: I have the lived  
 19 experience. I got my degree in  
 20 medicine in the early 1990s, and I  
 21 lived through these, you know, past  
 22 two and a half decades, and I  
 23 personally felt the pressures from  
 24 entities like the Joint Commission in  
 25 order to practice in a certain way.

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1 QUESTIONS BY MR. TSAI:

2 Q. And have you done any  
 3 quantitative analysis to tease out, let's  
 4 say, the role of hospital administrators, or  
 5 the role of third-party payers, in any  
 6 specific opioid prescribing decision of any  
 7 doctor in Cuyahoga and Summit County?

8 MR. ARBITBLIT: Object to form.

9 THE WITNESS: No.

10 QUESTIONS BY MR. TSAI:

11 Q. So moving on, just briefly, you  
 12 talked about the CME that you attended. It  
 13 was back in 2001.

14 A. Yes.

15 Q. So after attending that CME,  
 16 you didn't suddenly lose your independent  
 17 medical judgment, right?

18 You still had your own  
 19 independent medical judgment, you agree?

20 A. CME courses have an enormous  
 21 influence on the information that doctors  
 22 acquire on which to base their medical  
 23 judgment.

24 So I didn't lose my medical  
 25 judgment, but I can only make judgment based

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1 on the information that I have and the  
 2 misrepresentation at that CME and others like  
 3 it across the country.

4 Q. And you invoke your personal  
 5 experience?

6 A. Yes.

7 Q. So you didn't forget all of  
 8 your prior medical education and training  
 9 after leaving that -- how long was that  
 10 session? One hour? Day long?

11 A. (Witness nods head.)

12 MR. ARBITBLIT: Objection.

13 QUESTIONS BY MR. TSAI:

14 Q. Did you forget your medical  
 15 education and training?

16 MR. ARBITBLIT: Object to form.  
 17 THE WITNESS: Could you specify  
 18 what medical education and training  
 19 you're referring to?

20 QUESTIONS BY MR. TSAI:

21 Q. Yeah. Your medical school,  
 22 your residency, your fellowship, all of your  
 23 experience in the clinical setting, did the  
 24 CME make you forget all of that?

25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: I didn't forget  
 2 it, but medicine is a discipline in  
 3 which we must keep up with the science  
 4 as it evolves, and a very busy  
 5 clinician, including myself, does not  
 6 have the time to read every single  
 7 peer-reviewed article and dig into who  
 8 funded it or whether or not they  
 9 accurately represented their  
 10 information.

11 So we rely on continuing  
 12 medical education courses in order to  
 13 acquire that knowledge. So when I  
 14 went to that continuing medical  
 15 education course, I acquired a body of  
 16 knowledge that was not, in fact, based  
 17 in the evidence, that then influenced  
 18 my practice going forward and that of  
 19 my colleagues.

20 QUESTIONS BY MR. TSAI:

21 Q. And to pick up on what you  
 22 said, you have to keep up -- science evolves,  
 23 medicine evolves.

24 So that's how medicine works,  
 25 right? You have to make the best decisions

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1 that you can based on the scientific evidence  
 2 that's available --

3 MR. ARBITBLIT: Object to form.

4 QUESTIONS BY MR. TSAI:

5 Q. -- at the time of prescription;  
 6 do you agree with that?

7 MR. ARBITBLIT: Object to form.  
 8 THE WITNESS: As long as the  
 9 science is being accurately  
 10 represented.

11 QUESTIONS BY MR. TSAI:

12 Q. All right. So going back to  
 13 your TED Talk, if you could turn to page 5 of  
 14 that transcript?

15 A. Yeah.

16 Q. So starting on page 11, you  
 17 say --

18 A. Page 5 or page 11?

19 Q. Sorry, starting on page --  
 20 line 11 of page 5, you say, "The second big  
 21 invisible force driving this opioid epidemic  
 22 is the medicalization of poverty."

23 Do you see that?

24 A. Yes.

25 Q. Is it your opinion now that a

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1 big driver of the opioid epidemic is the  
 2 medicalization of poverty as you stated here  
 3 in 2017?

4 A. It's my opinion that the  
 5 medicalization of poverty is a factor in the  
 6 opioid epidemic, but not as big a factor as  
 7 supply.

8 Q. Okay. And have you done any  
 9 analysis to quantify the relative  
 10 significance of the contributions of the  
 11 factor of medicalization of poverty, to use  
 12 your words, and prescription opioid supply?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: I have not  
 15 personally done that analysis, but  
 16 there are others who I cite in my  
 17 report who talk about, again, as I've  
 18 answered in a previous question,  
 19 economic factors not being the primary  
 20 driver, and that supply of opioids in  
 21 a given region being the primary  
 22 driver of opioid use disorder and  
 23 opioid overdose in that region.

24 QUESTIONS BY MR. TSAI:

25 Q. So at this time what percentage

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1 or extent would you ascribe the contribution  
 2 of medicalization of poverty to the opioid  
 3 crisis?

4 MR. ARBITBLIT: Object to form.

5 THE WITNESS: It's hard for me  
 6 to put a percentage on it. I would  
 7 only say that the misrepresentation of  
 8 the evidence has been the primary  
 9 driver in the opioid epidemic.

10 In other words, the actions of  
 11 the defendants have been the primary  
 12 driver.

13 QUESTIONS BY MR. TSAI:

14 Q. Okay. But you can't say for  
 15 any actual prescription of an opioid that the  
 16 medicalization of poverty factor was not an  
 17 important contributing factor to that  
 18 decision?

19 MR. ARBITBLIT: Object to form.

20 QUESTIONS BY MR. TSAI:

21 Q. Is that right?

22 MR. ARBITBLIT: Object to form.

23 THE WITNESS: So can you  
 24 rephrase?

25 I'm sorry, there's a lot of

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1 double negatives, so it's hard for me  
 2 to track.

3 QUESTIONS BY MR. TSAI:

4 Q. Let me put it this way. Can  
 5 you reliably rule out the scenario that there  
 6 were prescriptions, or even a lot of  
 7 prescriptions, of opioid medications to  
 8 residents of Cuyahoga and Summit Counties  
 9 that were significantly influenced or driven,  
 10 as you've used, by this phenomenon of  
 11 medicalization of poverty?

12 MR. ARBITBLIT: Object to form.

13 THE WITNESS: I would -- I  
 14 can't reliably rule that out. I would  
 15 say that that may be a factor for  
 16 individuals in those counties, but  
 17 it's not the primary driver.

18 MR. ARBITBLIT: Can we take a  
 19 lunch break now? It's 12:15.

20 MR. TSAI: Sure.

21 VIDEOPHOTOGRAPHER: Okay. We're now  
 22 going off the record, and the time is  
 23 12:15.

24 (Off the record at 12:15 p.m.)

25 VIDEOPHOTOGRAPHER: We are now going

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1 back on the record, and the time is  
 2 12:53 p.m.

3 QUESTIONS BY MR. TSAI:

4 Q. Good afternoon.

5 A. Good afternoon.

6 Q. Just one background question.  
 7 When were you retained in this  
 8 case?

9 A. I was retained in January 2018.

10 Q. Do you agree that doctors are  
 11 trained to use their independent medical  
 12 judgment in making treatment or prescribing  
 13 decisions for their individual patients?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: I think that  
 16 doctors today are -- the training  
 17 around exercising their individual  
 18 medical judgment is much less of an  
 19 emphasis than it was, say, 30 or  
 20 40 years ago. I think there's much  
 21 more emphasis now on practicing what's  
 22 called evidence-based medicine.  
 23 That's a social movement that began in  
 24 the 1980s.

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1        medical training now on basing your  
 2        treatment decisions on what the  
 3        evidence shows.

## 4        QUESTIONS BY MR. TSAI:

5            Q.        In your opinion, do doctors  
 6        have a duty, an obligation, professionally,  
 7        to use their independent medical judgment in  
 8        making decisions for treatment or prescribing  
 9        based on their evaluation of their patients'  
 10      medical condition?

11            MR. ARBITBLIT: Object to form.

12            THE WITNESS: I think  
 13        exercising independent medical  
 14        judgment can be a good thing, if it's  
 15        informed by quality evidence, but if  
 16        independent decision-making is based  
 17        on a misrepresentation of the  
 18        evidence, that is a situation in which  
 19        that independent judgment does not  
 20        lead to good outcomes.

## 21        QUESTIONS BY MR. TSAI:

22            Q.        Have you reviewed the product  
 23        warning and labeling information for any of  
 24        the defendants' products in this case?

25            A.        Yes.

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1            Q.        Okay. So you would agree that  
 2        the risks of addiction and overdose with  
 3        respect to prescription opioids were clearly  
 4        disclosed, right upfront, in a black box,  
 5        front page, in bold letters for a doctor to  
 6        see?

7            MR. ARBITBLIT: Object to form.

8            THE WITNESS: Are you talking  
 9        about the black box warnings  
 10      specifically, when you say "in a black  
 11      box"?

## 12        QUESTIONS BY MR. TSAI:

13            Q.        Yes.

14            Have you reviewed the black box  
 15        opioid addiction and overdose warnings for  
 16        defendants' prescription opioids?

17            A.        Yes.

18            Q.        And so you agree that a doctor  
 19        practicing in Cuyahoga and Summit Counties  
 20        would have to try not to see the black box  
 21        warning about addiction and overdose risks to  
 22        be unaware of it?

23            MR. ARBITBLIT: Object to form.

24            Argumentative.

25            THE WITNESS: Maybe you could

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1        rephrase the question.

## 2        QUESTIONS BY MR. TSAI:

3            Q.        A doctor practicing in Cuyahoga  
 4        and Summit Counties would have readily  
 5        available in a black box on the front page of  
 6        the product warning information the  
 7        information warning about the risks of opioid  
 8        addiction and abuse; do you agree?

9            MR. ARBITBLIT: Object to form.

10            THE WITNESS: I would agree  
 11        that the labeling -- that some of the  
 12        labels at various points in time  
 13        included warnings about addiction, but  
 14        not the extent of the risk of  
 15        addiction, which I think would be very  
 16        important to include, especially given  
 17        the false messaging on the part of  
 18        defendants about the very low risk of  
 19        addiction to opioids prescribed for a  
 20        medical condition.

## 21        QUESTIONS BY MR. TSAI:

22            Q.        In your opinion, were the  
 23        warnings about the extent of risk of  
 24        addiction in the product warning information  
 25        that was approved by the US FDA inadequate?

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1            MR. ARBITBLIT: Object to form.  
 2            THE WITNESS: I think that  
 3        physicians were not adequately  
 4        informed about the risks of addiction  
 5        in prescribing of opioids.

6            To be adequately informed,  
 7        simply knowing that there is a risk is  
 8        insufficient. They would also need to  
 9        know about the extent of the risk.

## 10        QUESTIONS BY MR. TSAI:

11            Q.        Do you disagree with the FDA's  
 12        approval of prescription opioid medications  
 13        accompanied by those warnings?

14            MR. ARBITBLIT: Object to form.

15            THE WITNESS: So you're asking  
 16        me -- I'm sorry, maybe you can  
 17        rephrase the question, because I'm not  
 18        fully understanding your question.

## 19        QUESTIONS BY MR. TSAI:

20            Q.        Sure.

21            It sounds like you believe that  
 22        the FDA-approved warning information that  
 23        accompanied prescription opioids and were  
 24        provided to doctors was inadequate.

25            Is that your opinion?

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1 MR. ARBITBLIT: Object to form.  
 2 THE WITNESS: It's my opinion  
 3 that to be fully informed about the  
 4 risks of addiction to opioids, there  
 5 should be included that -- the extent  
 6 of the risk.

7 QUESTIONS BY MR. TSAI:

8 Q. And do you believe that the  
 9 warning information that, in fact,  
 10 accompanied prescription opioid medications  
 11 made and sold by the defendants and approved  
 12 by the FDA did not fully inform doctors of  
 13 that?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: So I have not  
 16 been asked specifically to offer an  
 17 opinion on the role of the FDA.

18 My understanding is that other  
 19 experts will give testimony on that.

20 So my focus is not on that in  
 21 my report.

22 QUESTIONS BY MR. TSAI:

23 Q. So you're not going to be  
 24 offering an opinion at trial telling the jury  
 25 that you think doctors weren't adequately

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1 informed by the information that they  
 2 received in the FDA-approved warning labels  
 3 that accompany prescription opioid  
 4 medications; is that correct?

5 MR. ARBITBLIT: Objection.  
 6 Objection. Argumentative. Misstates  
 7 the record.

8 THE WITNESS: Could you  
 9 rephrase the question?

10 QUESTIONS BY MR. TSAI:

11 Q. You're not going to be offering  
 12 an opinion at trial telling the jury that you  
 13 think doctors weren't adequately informed by  
 14 the information that they received in the  
 15 FDA-approved warning labels that accompanied  
 16 prescription opioid medications; is that  
 17 correct?

18 MR. ARBITBLIT: Objection.  
 19 Argumentative. Misstates the record.

20 THE WITNESS: Well, what I  
 21 would be testifying to a jury is that  
 22 there are many avenues by which  
 23 physicians get information about the  
 24 risks of a particular medicine that  
 25 they're prescribing, that the FDA

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1 warning label is one source of  
 2 information, but there are many other  
 3 sources, which I refer to in my  
 4 report, including continuing medical  
 5 education, peer-reviewed literature,  
 6 quality measures put forward by the  
 7 Joint Commission.

8 So the FDA labels are one part  
 9 of that.

10 QUESTIONS BY MR. TSAI:

11 Q. Any other sources of  
 12 information that doctors use in assessing the  
 13 risks and benefits and the propriety of  
 14 prescribing opioid medications?

15 A. Well, another unfortunate  
 16 source is pharmaceutical company detailing,  
 17 so representatives from the pharmaceutical  
 18 industry going to doctors to essentially  
 19 advertise their drug, which we know has an  
 20 impact on prescribing, even when that doctor  
 21 doesn't believe that they've been impacted by  
 22 that contact.

23 So that's another source.

24 Q. You're familiar with the  
 25 Cleveland Clinic?

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1 A. Yes, I guess.

2 Q. In your opinion, do all the  
 3 doctors at Cleveland Clinic who wrote  
 4 prescriptions of opioid medications for their  
 5 patients do so for the wrong reasons?

6 MR. ARBITBLIT: Object to form.  
 7 THE WITNESS: I would never  
 8 make a broad, general claim like that.

9 QUESTIONS BY MR. TSAI:

10 Q. All right. Do you -- let's  
 11 take a doctor at the Cleveland Clinic who  
 12 wrote prescriptions for his or her patients  
 13 for a defendant manufacturer who distributed  
 14 opioid medication.

15 Have you -- do you have any  
 16 reason to doubt that the doctor wrote it for  
 17 good reasons?

18 MR. ARBITBLIT: Object to form.  
 19 THE WITNESS: What do you mean  
 20 by "good reasons"?

21 QUESTIONS BY MR. TSAI:

22 Q. For a legitimate and  
 23 appropriate and necessary medical condition.

24 MR. ARBITBLIT: Object to form.

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1 QUESTIONS BY MR. TSAI:

2 Q. Have you reviewed any medical  
 3 records or any other information that allows  
 4 you to specify an instance where -- to doubt  
 5 that a doctor wrote an opioid prescription  
 6 for good reasons?

7 MR. ARBITBLIT: Object to form.

8 THE WITNESS: I think that  
 9 doctors trained in the 1990s and early  
 10 aughts continuing to today were  
 11 misinformed about the benefits and  
 12 risks of opioids such that there has  
 13 been an enormous amount of prescribing  
 14 opioids absent evidence to support  
 15 their use, but not because those  
 16 doctors are not good doctors.

17 In most cases they're  
 18 well-educated and well-intentioned,  
 19 but they have been led to believe  
 20 something false about the benefits and  
 21 risks of opioids such that their  
 22 prescribing has led to the harm of  
 23 their patients. And I venture to say  
 24 that that includes doctors at the  
 25 Cleveland Clinic.

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1 QUESTIONS BY MR. TSAI:

2 Q. So let me give you a particular  
 3 example.  
 4 Do you agree that the most  
 5 common error made by physicians in using  
 6 opioid analgesics for pain relief is failure  
 7 to provide a sufficient dose to achieve  
 8 optimal relief?

9 MR. ARBITBLIT: Object to form.

10 THE WITNESS: I don't agree  
 11 with that.

12 QUESTIONS BY MR. TSAI:

13 Q. Okay. Tell me why you don't  
 14 agree with that statement.

15 A. I think it's extremely  
 16 difficult to determine what an optimal dose  
 17 would be. There is no pain-o-meter, so we  
 18 can't really objectively assess what a  
 19 patient's pain is. The way that we use  
 20 opioids to treat pain is very much based on  
 21 what the prevailing practice is in a given  
 22 institution, hospital, community, country, at  
 23 that time.

24 And so I would argue that the  
 25 most common error made by physicians in using

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1 opioid analgesics for pain relief is the  
 2 tendency to prescribe too high a dose and for  
 3 too long a duration, and I think we have  
 4 proof of that given that we are in the midst  
 5 of an opioid epidemic, which is first and  
 6 foremost an epidemic of overprescribing.

7 Q. So just to be clear, there's no  
 8 thermometer analog, glucose meter analog, to  
 9 actually measure how much someone is  
 10 suffering from pain; you agree?

11 A. Yes.

12 Q. And because it's extremely  
 13 difficult to determine what an optimal dose  
 14 is, you would agree that the decision, with  
 15 respect to dose of an opioid medication, is  
 16 highly individualized?

17 MR. ARBITBLIT: Object to form.

18 THE WITNESS: No, I would  
 19 disagree with that, because we have a  
 20 wealth of evidence showing that  
 21 opioids prescribed above a certain  
 22 dose are highly dangerous and no  
 23 reliable evidence showing efficacy  
 24 used long term in the treatment of  
 25 chronic pain.

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1 QUESTIONS BY MR. TSAI:

2 Q. Do you agree that doctors at  
 3 the Cleveland Clinic followed treatment and  
 4 prescribing standards?

5 MR. ARBITBLIT: Object to form.  
 6 THE WITNESS: The standards for  
 7 treatment and prescribing over the  
 8 last three decades have been highly  
 9 manipulated by the defendants, such  
 10 that treatment standards today are not  
 11 based on the evidence.

12 QUESTIONS BY MR. TSAI:

13 Q. Would you agree that the good  
 14 doctors in Cuyahoga and Summit Counties and  
 15 Cleveland Clinic know how to evaluate for  
 16 themselves an article they read in a medical  
 17 journal?

18 MR. ARBITBLIT: Object to form.

19 THE WITNESS: I believe that  
 20 most doctors, including those in  
 21 Cuyahoga and Summit County, don't have  
 22 the time or the training to read  
 23 peer-reviewed articles at the depth  
 24 required to appreciate the information  
 25 therein.

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1           And furthermore, the  
 2         articles -- many of the articles that  
 3         they have been exposed to have been  
 4         manipulated by the defendants and are  
 5         a misrepresentation of the evidence,  
 6         such that doctors in Summit and  
 7         Cuyahoga County cannot use their good  
 8         judgment in individual cases because  
 9         they don't have accurate evidence to  
 10        rely upon to inform that judgment.

11        QUESTIONS BY MR. TSAI:

12        Q.       Would you agree that the good  
 13      doctors at Cleveland Clinic and throughout  
 14      Cuyahoga and Summit Counties know how to  
 15      evaluate for themselves the information in an  
 16      FDA-approved label?

17           MR. ARBITBLIT: Object to form.

18           THE WITNESS: I would venture  
 19        to guess that many doctors don't rely  
 20        on the FDA label alone. It's not even  
 21        a guess. Doctors do not rely on the  
 22        FDA label alone in order to inform  
 23        their decisions.

24           They're much more likely to be  
 25        influenced by continuing medical

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1           education courses they've attended, by  
 2         the quality measures of their  
 3         hospitals, and something as simple as  
 4         how the practice of pain is conducted  
 5         in that hospital.

6        QUESTIONS BY MR. TSAI:

7        Q.       So am I hearing that your null  
 8        hypothesis is that when a doctor, in any  
 9        given locality, prescribes an opioid  
 10       medication, then they have been duped into  
 11       that decision?

12        A.       Exactly, yes.

13        Q.       And you've written and stated  
 14        in various places that doctors themselves  
 15        must bear some responsibility for the opioid  
 16       epidemic, correct?

17        A.       Yes.

18        Q.       Okay. If a doctor in Cuyahoga  
 19      and Summit Counties was prescribing opioid  
 20      medications to residents of the county purely  
 21      for their own personal profit, knowing that  
 22      those individuals really didn't need the  
 23      medicines for any medical pain condition, you  
 24      would agree that doctor is violating medical  
 25      ethics?

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1           MR. ARBITBLIT: Object to form.  
 2           THE WITNESS: I would agree  
 3        that such a doctor is violating  
 4        medical ethics, but I have also  
 5        written and published on the problem  
 6        of prescribing, and we have shown,  
 7        using Medicare Part D data, that the  
 8        increase in opioid prescribing in this  
 9        country over the past three decades  
 10       was not primarily due to a small  
 11       subset of prolific prescribers or  
 12       so-called pill mill doctors, unethical  
 13       doctors, doctors who have lost their  
 14       moral compass. Those types of doctors  
 15       have always existed and will always  
 16       exist.

17           In fact, the increase in opioid  
 18        prescribing in this country has been  
 19        primarily driven by all types of  
 20        doctors across all types of  
 21        specialties because of the major  
 22        paradigm shift in the use of opioids  
 23        for minor and chronic pain conditions  
 24        as a result of misrepresentation of  
 25        the evidence on the part of the

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1           defendants.

2        QUESTIONS BY MR. TSAI:

3        Q.       If a doctor in the counties was  
 4        prescribing opioid medications purely for  
 5        their personal profit, knowing that the  
 6        individual they're providing opioids to did  
 7        not have a legitimate pain condition, would  
 8        you agree that doctor is committing a crime?

9           MR. ARBITBLIT: Object to form.

10          THE WITNESS: I would agree  
 11        that that doctor is committing a  
 12        crime, but I think doctors like that  
 13        constitute a small subset of the  
 14        overall opioid prescriptions.

15        QUESTIONS BY MR. TSAI:

16        Q.       Okay. Do you have a method of  
 17        assigning the degree to which doctors in  
 18        Cuyahoga and Summit Counties, in your words,  
 19        bear some responsibility for the  
 20        overprescribing of opioids for chronic pain  
 21        versus the contribution of any of the other  
 22        factors we've discussed today?

23           MR. ARBITBLIT: Object to form.

24          THE WITNESS: I believe that  
 25        the majority of opioid prescribers in

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1 Cuyahoga and Summit County and the  
 2 rest of the country are  
 3 well-intentioned doctors who were led  
 4 to believe that opioids work for  
 5 chronic pain and that the risks are  
 6 low, including the risk of addiction  
 7 and death.

8 QUESTIONS BY MR. TSAI:

9 Q. Have you reviewed any materials  
 10 or have any other basis, or conducted any  
 11 kind of quantitative analysis, to reliably  
 12 rule out the likelihood that doctors in  
 13 Cuyahoga and Summit Counties, in your words,  
 14 bear some responsibility for the  
 15 overprescribing of opioids for chronic pain  
 16 to individuals in those counties?

17 MR. ARBITBLIT: Object to form.

18 THE WITNESS: I think that  
 19 prescribers bear responsibility in the  
 20 sense that they were misled by the  
 21 defendants, and they weren't more  
 22 questioning of what they were taught  
 23 in the '90s and early aughts.

24 And so they bear some  
 25 responsibility in the sense of not

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1 having been more skeptical about the  
 2 use of opioids, but in general, I  
 3 believe that doctors were primarily  
 4 duped by the defendants into  
 5 prescribing opioids for chronic pain  
 6 and minor pain conditions.

7 QUESTIONS BY MR. TSAI:

8 Q. And can you point to me  
 9 anywhere where you have quantified the degree  
 10 or extent of, as you say, the responsibility  
 11 of prescribers in Cuyahoga and Summit  
 12 Counties due to their lack of diligence or  
 13 negligence?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: It's not a lack  
 16 of diligence or negligence. It's a  
 17 matter of a paradigm shift in the way  
 18 that doctors were pressured into  
 19 treating pain with opioids, and I have  
 20 quantified that in an article that we  
 21 published in The Journal of the  
 22 American Medical Association, showing  
 23 that the increase in opioid  
 24 prescribing based on the Medicare  
 25 Part D database -- which is a database

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1 that covers the entire United States,  
 2 showing that increased prescribing has  
 3 not been driven primarily by a small  
 4 subset of prolific prescribers, but by  
 5 a paradigm shift in prescribing  
 6 opioids across all different types of  
 7 prescribers such that we were all  
 8 prescribing more opioids as a result  
 9 of misrepresentation of the evidence  
 10 by the defendants.

11 QUESTIONS BY MR. TSAI:

12 Q. And what was the quantification  
 13 of the degree of responsibility for  
 14 physicians in your analysis?

15 MR. ARBITBLIT: Object to form.

16 THE WITNESS: I feel like I've  
 17 answered that question.

18 QUESTIONS BY MR. TSAI:

19 Q. Well, if there's an amount or a  
 20 number, would that be in the article?

21 MR. ARBITBLIT: Object to form.

22 QUESTIONS BY MR. TSAI:

23 Q. Or was it a qualitative  
 24 analysis?

25 A. It was a quantitative analysis.

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1 The article uses the  
 2 quantitative analysis of the Medicare Part D  
 3 database to demonstrate that pill mill  
 4 doctors, doctors who, as you suggested, are  
 5 committing crimes are not the major factor.  
 6 Those doctors exist.

7 Their behavior is  
 8 reprehensible, but the vast majority of  
 9 opioids prescribed in this country are  
 10 prescribed not by such ethically compromised  
 11 doctors, but by well-intentioned doctors who  
 12 have been prescribing according to the  
 13 misrepresentation of the evidence made  
 14 available to them by the actions of the  
 15 defendants.

16 (Lembke Exhibit 11 marked for  
 17 identification.)

18 BY MR. TSAI:

19 Q. So I'll introduce exhibit next  
 20 in order. So this is a --

21 A. I don't have it yet. Just grab  
 22 it?

23 Q. I'll describe it to you while  
 24 the court reporter is marking it.

25 I'll represent to you that this

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1 is a press release from the US Department of  
2 Justice. It's dated August 22, 2018.

3 Were you aware of that press  
4 conference that happened right in Cleveland,  
5 Ohio?

6 A. I might have read about it if  
7 it was in the public domain. I don't  
8 specifically recall.

9 Q. Okay. So if you could turn to  
10 page -- starting on page 3 of this exhibit,  
11 press release, and I would just like to focus  
12 you in on this issue. It is the third  
13 paragraph from the bottom, and I'll just read  
14 it.

15 "My third announcement arises  
16 from Operation Darkness Falls, a joint  
17 operation against dark net fentanyl  
18 traffickers by the FBI, the IRS, our Postal  
19 Inspectors and Homeland Security  
20 investigators, again right here in northern  
21 Ohio.

22 "Today I'm announcing that this  
23 office has charged a husband and wife who, at  
24 the time of their arrest, were the most  
25 prolific dark fentanyl vendor in the United

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1 States and the fourth most prolific on earth.  
2 They were known online as MH4Life.

3 "Last July, the Department of  
4 Justice seized Alpha Bay, which was the  
5 largest dark net marketplace in history."

6 Moving on to page 3. "This  
7 site hosted some 220,000 drugs and countless  
8 synthetic opioid overdoes, including the  
9 tragic deaths of a 13-year-old," and it goes  
10 on with a lot more details.

11 Are you familiar in your own  
12 clinical work with patients with opioid use  
13 disorder with individuals who are addicted to  
14 illegal or synthetic fentanyl?

15 MR. ARBITBLIT: Object to form.

16 The question is unrelated to the  
17 preface.

18 THE WITNESS: So just to  
19 restate your question, you're asking  
20 me if I'm familiar in my clinical work  
21 with patients with opioid use disorder  
22 with individuals who are addicted to  
23 illegal or synthetic fentanyl?

24 QUESTIONS BY MR. TSAI:

25 Q. Have you worked with patients

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1 who are addicted to illegal, synthetic  
2 fentanyl?

3 A. I have worked with patients who  
4 are addicted to illegal opioids.

5 Q. Okay. And we can agree that  
6 these dark net fentanyl dealers referred to  
7 in the Department of Justice announcement are  
8 criminals?

9 MR. ARBITBLIT: Object to form.

10 THE WITNESS: I'm not a lawyer,  
11 I haven't reviewed this, but it does  
12 sound like they are criminals.

13 QUESTIONS BY MR. TSAI:

14 Q. And if members of these dark  
15 net fentanyl and other illegal drug selling  
16 operation came into court and said, you know,  
17 "Based on Dr. Lembke's expert opinion,  
18 Gateway and Tsunami theories, I'm really not  
19 guilty of anything; it's really the legal  
20 drug manufacturers' and distributors' and  
21 pharmacies' fault," would you support that  
22 argument?

23 MR. ARBITBLIT: Object to form.

24 Argumentative.

25 THE WITNESS: The individuals

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1 being accused here are the dealers; is  
2 that right?

3 QUESTIONS BY MR. TSAI:

4 Q. They are the operators of these  
5 dark net fentanyl marketplaces.

6 A. Okay.

7 MR. ARBITBLIT: There's no  
8 question pending. That's a statement.  
9 Wait for a question.

10 THE WITNESS: Okay. Maybe you  
11 could rephrase your question.

12 QUESTIONS BY MR. TSAI:

13 Q. I'm just kind of seeing the  
14 bounds of your opinion.

15 So if these dark net fentanyl  
16 dealers said, "Well, you know, everyone has  
17 been duped by this climate that you referred  
18 to, I'm not guilty of anything, it's the  
19 legal prescription, supply companies'  
20 businesses" --

21 MR. ARBITBLIT: Object to form.

22 QUESTIONS BY MR. TSAI:

23 Q. -- "that should be indicted,"  
24 would you agree with that argument?

25 MR. ARBITBLIT: Object to form.

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1 Argumentative.  
 2 THE WITNESS: No, and that's  
 3 not the argument that I've made.  
 4 QUESTIONS BY MR. TSAI:  
 5 Q. So you agree that members of  
 6 these dark net fentanyl and other illegal  
 7 drug selling operations, including right here  
 8 in northern Ohio, are responsible for their  
 9 own criminal acts?  
 10 A. Yes.  
 11 Q. Okay. In other words, the  
 12 existence of the legal prescription opioid  
 13 medication business is not a defense to the  
 14 crime of trafficking and possession of street  
 15 heroin and other illegal opioids?  
 16 MR. ARBITBLIT: Object to form.  
 17 THE WITNESS: I think without  
 18 knowing more, it's difficult for me to  
 19 comment, but most people who deal  
 20 opioids are also themselves addicted  
 21 to opioids. So if these individuals  
 22 have become addicted to opioids, then  
 23 that would be a mitigating factor in  
 24 considering their punishment.  
 25 And I do think that the problem

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1 more broadly of opioids, including  
 2 illicit opioids, is directly linked to  
 3 the problem of overprescribing medical  
 4 opioids as evidenced by the graph  
 5 showing that as opioid prescriptions  
 6 have increased over the past 15 to  
 7 20 years, opioid overdose deaths have  
 8 increased in lockstep.  
 9 QUESTIONS BY MR. TSAI:  
 10 Q. So you're not prepared to say  
 11 that with respect to these illegal fentanyl  
 12 operations that there is no connection to any  
 13 defendants' conduct?  
 14 MR. ARBITBLIT: Object to form.  
 15 Argumentative. Misstates the record.  
 16 THE WITNESS: I think that  
 17 there's a potential for a connection  
 18 to the defendants' conduct.  
 19 QUESTIONS BY MR. TSAI:  
 20 Q. Okay. Would you be speculating  
 21 about that connection, or do you have any  
 22 specific basis that any defendant played any  
 23 part in these illegal fentanyl marketplaces?  
 24 MR. ARBITBLIT: Object to form.  
 25 Argumentative and compound.

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1 THE WITNESS: The connection to  
 2 this conduct is a population of  
 3 individuals who have become addicted  
 4 to opioids as a result of the  
 5 defendants' conduct, who are then  
 6 seeking out illicit opioids as part of  
 7 their addiction. That, to me, is a  
 8 link.  
 9 QUESTIONS BY MR. TSAI:  
 10 Q. And you would support a  
 11 defense, a mitigation defense, for these dark  
 12 net fentanyl dealers based upon this idea?  
 13 MR. ARBITBLIT: Objection.  
 14 Argumentative. Misstates the  
 15 testimony.  
 16 THE WITNESS: I think you're --  
 17 maybe I'm misunderstanding you, but I  
 18 think you're making a connection that  
 19 I'm not making between the defense of  
 20 these dark net dealers and the fact  
 21 that we have an opioid epidemic.  
 22 Those, to me, are different  
 23 things.  
 24 I don't know enough about the  
 25 specifics of these dark net dealers to

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1 weigh in on any kind of defense for  
 2 them, but I do think that there is a  
 3 link between the fact that they have a  
 4 booming market for their illicit  
 5 opioids and the fact that the  
 6 defendants' conduct contributed to an  
 7 opioid epidemic based on  
 8 misrepresentation of the evidence that  
 9 led to physicians who were duped  
 10 overprescribing medical opioids.  
 11 QUESTIONS BY MR. TSAI:  
 12 Q. And the link that you posited,  
 13 does that have any basis, anything specific  
 14 to these individuals that are called out in  
 15 this announcement?  
 16 MR. ARBITBLIT: Object to form.  
 17 THE WITNESS: Well, you are the  
 18 one who asked me to speculate based on  
 19 this, so I'm doing my best to try to  
 20 answer your question based on very  
 21 little information about these  
 22 individuals.  
 23 QUESTIONS BY MR. TSAI:  
 24 Q. Okay. So other than this, you  
 25 have not reviewed or are familiar with any

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1 conduct in relation to these dark net  
 2 fentanyl criminals; is that correct?  
 3 MR. ARBITBLIT: Object to form.  
 4 THE WITNESS: I feel like I  
 5 answered the question.

6 QUESTIONS BY MR. TSAI:

7 Q. In preparation for your book,  
 8 you conducted interviews with patients who  
 9 received opioids and prescribers of opioids,  
 10 correct?

11 A. Yes.

12 Q. Okay.

13 MR. TSAI: Could we get Tab 29?  
 14 (Lembke Exhibit 12 marked for  
 15 identification.)

16 QUESTIONS BY MR. TSAI:

17 Q. So just to start out, in your  
 18 report on page 80, you talked about  
 19 manipulative behaviors of patients in  
 20 attempting to obtain opioid drugs from their  
 21 doctors.

22 Do you agree that patients  
 23 themselves engage in manipulative behaviors  
 24 to attempt to obtain opioid medications from  
 25 their doctor?

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1 A. Yes, but it's important to  
 2 understand that behavior as part of the  
 3 disease of addiction.  
 4 Q. Okay. What types of  
 5 manipulative behaviors are examples that  
 6 you're familiar with?

7 A. Doctors -- a patient's going to  
 8 multiple prescribers to get the same or a  
 9 similar prescription. Patients exaggerating  
 10 their pain symptoms to get a certain type of  
 11 prescription. Patients claiming to be  
 12 allergic to a certain medication in order to  
 13 get the specific medication that they want.

14 Those are some examples.

15 Q. Okay. So boiling it all down,  
 16 in those instances that you've described, the  
 17 patients are lying to their own doctors,  
 18 correct?

19 MR. ARBITBLIT: Object to form.

20 THE WITNESS: Yes.

21 QUESTIONS BY MR. TSAI:

22 Q. And in your opinion, do you  
 23 believe that patients bear responsibility for  
 24 their decisions to lie to their doctors?

25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: To me, the lying  
 2 is a result of their disease of  
 3 addiction, so in some sense they do  
 4 not actually have full capacity to be  
 5 responsible for those actions because  
 6 they're driven by the intense  
 7 physiologic need to get more opioids.

8 QUESTIONS BY MR. TSAI:

9 Q. Have you reviewed any  
 10 information or have any other basis to  
 11 reliably rule out the likelihood that with  
 12 respect to opioids, patients in Cuyahoga and  
 13 Summit Counties lied to and manipulated their  
 14 doctors?

15 A. I don't believe that Cuyahoga  
 16 and Summit Counties are an exception to  
 17 anywhere else in the United States. And that  
 18 those individuals in Summit and Cuyahoga  
 19 County who have become addicted to opioids  
 20 may very well lie to and manipulate their  
 21 doctors as part of their disease of  
 22 addiction.

23 Q. So if you could turn to your  
 24 Tab 29, and if you could go to the fourth  
 25 page in that packet. Is that right?

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1 Actually, yeah, if you could --  
 2 these are the handwritten notes that were  
 3 provided by your counsel to us prior to this  
 4 deposition. If you could -- and they weren't  
 5 numbered.

6 If you could turn to what is  
 7 sequentially page 9 of this packet, and if it  
 8 would help, there's -- in the middle of that  
 9 page, there is a heading or a phrase "how to  
 10 fool doctors."

11 Do you see that?

12 A. Yes.

13 Q. So part of this is just a  
 14 mechanical exercise to make sure I'm reading  
 15 your handwriting.

16 Let me read it. "How to fool  
 17 doctors: After the surgery it was easy to  
 18 get, very patient. I would never try to push  
 19 or inject what I was looking for unless it  
 20 was the absolute thing to do. Easy on the --  
 21 for them, for the narcotics, treat him, get  
 22 rid of him, seems like a nice guy, try to  
 23 fool him as inconspicuously as you can."

24 Does that look about right?

25 A. Yes.

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1 Q. Can you explain the context of  
 2 the meaning of these notes?  
 3 A. Sure.  
 4 So this is a qualitative  
 5 interview I did with a patient of mine who  
 6 became addicted to opioids through a doctor's  
 7 prescription, and he was somebody who was in  
 8 recovery from alcohol use disorder for over a  
 9 decade when he developed low back pain and  
 10 was prescribed opioids for that low back  
 11 pain.

12 That continued for some time,  
 13 and he -- because of the phenomenon of  
 14 cross-addiction, he immediately felt the same  
 15 physiologic urges that he had had with  
 16 alcohol but now replaced by opioids, and he  
 17 continued to go to his doctor to ask for more  
 18 opioids. He felt he was in pain, but he also  
 19 felt on some level that he was craving  
 20 opioids because of his addiction.

21 And then he -- when the doctor  
 22 refused after a number of weeks to refill  
 23 that prescription, he began going to a  
 24 variety of walk-in clinics in order to get  
 25 opioids from the doctors working there. And

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1 he developed a kind of repertoire of  
 2 behaviors that he used in order to get this  
 3 prescription that he wanted. Namely, a  
 4 prescription for opioids.

5 I will add that he is a very  
 6 lovely man, and that because of his exposure  
 7 to opioids through a medical prescription, he  
 8 relapsed his addiction and engaged in these  
 9 manipulative behaviors as a symptom of his  
 10 addiction.

11 Q. So this individual for his  
 12 particular case history, he had alcohol use  
 13 disorder --

14 A. Yes.

15 Q. -- before ever being exposed to  
 16 prescription opioids?

17 A. That's correct.

18 Q. Okay. And this individual,  
 19 this is an example of someone who is lying to  
 20 his doctor or multiple doctors in order to  
 21 get opioids?

22 MR. ARBITBLIT: Object to form.

23 THE WITNESS: Yes. Uh-huh.

24 MR. TSAI: Can we go off the  
 25 record?

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1 VIDEOGRAPHER: Okay. We are  
 2 now going off the record, and the time  
 3 is 1:32 p.m.

4 (Off the record at 1:32 p.m.)

5 VIDEOGRAPHER: We are now going  
 6 back on the record, and the time is  
 7 1:34 p.m.

8 QUESTIONS BY MR. TSAI:

9 Q. So staying on that page, if you  
 10 could go down to the following paragraph. I  
 11 just wanted to make sure I read this  
 12 correctly in your notes. I have it as, "Some  
 13 colleagues' goals is just to keep up  
 14 percentage of money, just get them out the  
 15 door, time and space, one trusted colleague  
 16 said 'just give them what they want.'"

17 Did I read that accurately?

18 A. I'm sorry, where -- is that the  
 19 same page or --

20 Q. Sorry. It is actually -- if  
 21 you, in this packet, go to the -- do you see  
 22 it near the end, this blue space?

23 A. The blue -- the first blue  
 24 space?  
 25 Q. The last blue space.

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1 A. The last blue space, okay.  
 2 And it is after the last blue  
 3 space?

4 Q. It's before.

5 If you could flip four pages  
 6 before that, please, and as a marker the top  
 7 line says "fee structure."

8 MR. TSAI: Can we go off the  
 9 record? Maybe it will just be easier  
 10 for me to point it out.

11 VIDEOGRAPHER: We are going off  
 12 the record. And the time is 1:35 p.m.

13 (Off the record.)

14 We're still on. Back on the  
 15 record. It's 1:36 p.m.

16 QUESTIONS BY MR. TSAI:

17 Q. So on that page, the paragraph,  
 18 I would say the second paragraph from the  
 19 bottom, I'm going to read it to see if I have  
 20 it accurately.

21 It says, "Some colleagues'  
 22 goals is just to keep up percentage of money,  
 23 just get them out the door, time and space.  
 24 One trusted colleague 'just said give them  
 25 what they want.'"

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1                   Did I read that accurately?  
 2       A.     Not quite.  
 3       Q.     Can you read it then?  
 4       A.     Sure.  
 5                   "Some colleagues' goals is just  
 6     to keep the ED moving, just get them out the  
 7     door, time and space."  
 8       Q.     "One trusted colleague said  
 9     'just give them what they want'?"  
 10      A.     Yes.  
 11      Q.     And what does "the ED moving"  
 12    refer to?  
 13      A.     This is the emergency  
 14    department.  
 15      Q.     Okay. And generally, this  
 16    packet of notes, you recognize this as a true  
 17    and correct copy of your notes?  
 18      A.     Yes, I do.  
 19      Q.     Okay. And is this an example  
 20    of medical practitioners, doctors, who feel  
 21    pressured to, in your words, follow the  
 22    assembly line of prescribing and treating  
 23    patients?  
 24      A.     Yes, it is.  
 25      MR. TSAI: I'm going to go off

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1                   the record. I would like to take a  
 2                   quick break. Thanks.  
 3                   VIDEOPHOTOGRAPHER: We're going off  
 4     the record, and the time is 1:37 p.m.  
 5                   (Off the record at 1:37 p.m.)  
 6                   VIDEOPHOTOGRAPHER: We are now going  
 7     back on the record, and the time is  
 8     1:56 p.m.  
 9                   (Lembke Exhibit 13 marked for  
 10    identification.)  
 11    QUESTIONS BY MR. TSAI:  
 12      Q.     So the next exhibit is  
 13    Appendix I to your report, and it has five  
 14    sections. Section B relates to Mallinckrodt.  
 15                   Can you turn to that?  
 16      A.     Sure.  
 17      Q.     So, first of all, have you  
 18    reviewed any information that you can point  
 19    to or have any other basis to say that any of  
 20    the statements that you attribute to  
 21    Mallinckrodt in Appendix I.B of your report  
 22    were actually seen by any specific doctor or  
 23    other person in Cuyahoga and Summit Counties?  
 24      A.     I don't have specific examples,  
 25    but I do believe these misrepresentations

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1    were widely disseminated, including in Summit  
 2    and Cuyahoga Counties.  
 3       Q.     So are you speculating that  
 4     they would be seen by doctors in Cuyahoga and  
 5     Summit Counties but cannot point to any  
 6     specific basis to back that up? Is that fair  
 7     to say?  
 8       MR. ARBITBLIT: Object to form.  
 9       THE WITNESS: Because these  
 10    misrepresentations were so deeply  
 11    interwoven into medical education, it  
 12    would be hard for me to believe that  
 13    physicians in Summit and Cuyahoga  
 14    Counties hadn't seen these  
 15    misrepresentations, but I cannot point  
 16    to any specific examples.  
 17    QUESTIONS BY MR. TSAI:  
 18      Q.     And when you talked to doctors  
 19    after your pair of talks last year in Ohio,  
 20    did any of those doctors who practice in  
 21    Cuyahoga and Summit Counties tell you that  
 22    they relied on any of the statements that you  
 23    attribute to Mallinckrodt specifically?  
 24       MR. ARBITBLIT: Object to form.  
 25       THE WITNESS: The doctors that

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1    I spoke with validated that the  
 2    misrepresentations laid out here in  
 3    this section under Mallinckrodt were  
 4    misrepresentations that they had been  
 5    the recipients of in their medical  
 6    training and that had led them to  
 7    prescribe opioids in a way that they  
 8    now realize was not evidence based.  
 9    QUESTIONS BY MR. TSAI:  
 10     Q.     Did anyone use the word  
 11    "Mallinckrodt"?

12     A.     No, not that I recall.

13     Q.     Did anyone use the word -- any  
 14    of the products that are -- that Mallinckrodt  
 15    made specifically?

16     A.     Not that I recall.

17     Q.     Okay. Have you done any  
 18    analysis to determine whether or to what  
 19    extent Mallinckrodt's marketing of opioid  
 20    products, specifically Mallinckrodt,  
 21    influenced prescribing decisions or rates in  
 22    Cuyahoga and Summit Counties?

23       MR. ARBITBLIT: Object to form.

24       THE WITNESS: Mallinckrodt held  
 25    the Train-the-Trainer events which

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1       communicated these misrepresentations  
 2       to individuals who then went  
 3       throughout the country disseminating  
 4       these misrepresentations, and I don't  
 5       have any specific examples, but I  
 6       wouldn't be surprised if they  
 7       disseminated these misrepresentations  
 8       also in Summit and Cuyahoga Counties.

9           Also Mallinckrodt promoted a  
 10      book through the CARES Alliance called  
 11      Defeat Chronic Pain Now!, and I  
 12      wouldn't be surprised if that book was  
 13      read by providers in Cuyahoga and  
 14      Summit County and that book contained  
 15      these misrepresentations.

16 QUESTIONS BY MR. TSAI:

17       Q.     So you say you wouldn't be  
 18      surprised, but can you point to anything in  
 19      your materials that you've provided to us  
 20      that specifically isolates the contribution  
 21      of Mallinckrodt's conduct to promotional  
 22      activity with respect to opioid prescribing  
 23      or any adverse event in Cuyahoga and Summit  
 24      County?

25           MR. ARBITBLIT: Object to form.

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1           THE WITNESS: No, I cannot, but  
 2       as I said before, I don't think  
 3       Cuyahoga and Summit Counties are an  
 4       exception to the national trend.  
 5           (Lembke Exhibit 14 marked for  
 6       identification.)

7 QUESTIONS BY MR. TSAI:

8       Q.     So the next exhibit -- if you  
 9       could turn to page 4 of the Mallinckrodt  
 10      section.

11       A.     Yes.

12       Q.     So the topic under Number 5 is  
 13      "Abuse-Deterrent Formulations Prevent  
 14      Addiction," and you reference this exhibit,  
 15      which is the next exhibit -- it starts  
 16      MNK-T1. The range is 529004 to 529126.

17           And once that's introduced, I  
 18      would like you to turn to the -- yeah.

19           If you could turn to the page  
 20      that's -- has -- ends in Bates Number 9077.

21       A.     529077?

22       Q.     529077, correct.

23           Do you have any basis to say  
 24      that Mallinckrodt ever characterized one of  
 25      its own opioid products specifically as abuse

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1       deterrent?  
 2           MR. ARBITBLIT: Object to form.  
 3           THE WITNESS: I believe that in  
 4       one -- in the Mallinckrodt  
 5       Train-the-Trainer events, there were  
 6       speakers who claimed that  
 7       abuse-deterrent formulations make  
 8       abuse more difficult, and since  
 9       Mallinckrodt sponsored that event, the  
 10      implication is that that would include  
 11      Mallinckrodt's products.

12       MR. TSAI: I'll move to strike.

13 QUESTIONS BY MR. TSAI:

14       Q.     My question was: Can you name  
 15      a particular product made by Mallinckrodt  
 16      that Mallinckrodt characterized as being  
 17      abuse deterrent?

18           MR. ARBITBLIT: Object to form.

19 QUESTIONS BY MR. TSAI:

20       Q.     And if so, could you --  
 21       A.     Broadly speaking, I would say  
 22      that Mallinckrodt, like other defendants,  
 23      misrepresented the risk of addiction to  
 24      opioids prescribed for chronic pain, and in  
 25      that sense communicated that the risk was low

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1       or nonexistent, implying abuse deterrent.  
 2           MR. TSAI: And for the record,  
 3       again, I'll move to strike, and that  
 4       is absolutely not responsive to my  
 5       question.

6 QUESTIONS BY MR. TSAI:

7       Q.     Let me say it again. Can you  
 8       name a particular product made or sold by  
 9       Mallinckrodt that Mallinckrodt characterized  
 10      as this product is abuse deterrent?

11           MR. ARBITBLIT: Object to form.

12           THE WITNESS: I think that  
 13      Mallinckrodt and the other defendants  
 14      in many ways characterized all of  
 15      their opioids as abuse deterrent, as  
 16      long as they were being prescribed by  
 17      a doctor for a medical condition.

18 QUESTIONS BY MR. TSAI:

19       Q.     Okay. And you cited this  
 20      document, and you specifically cited in your  
 21      report at page 529077, and this says,  
 22      "Abuse-deterrent formulations, as the name  
 23      implies, make the abuse of the medication  
 24      more difficult. Recently the FDA released a  
 25      guidance statement pertaining to the

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1 evaluation and labeling of certain  
 2 abuse-deterring formulations."  
 3 That's what you cited in your  
 4 report.

5 There's nothing here specific  
 6 to a Mallinckrodt product; do you agree?

7 MR. ARBITBLIT: Object to form.

8 THE WITNESS: I agree.

9 QUESTIONS BY MR. TSAI:

10 Q. If you could now go to -- back  
 11 to Mallinckrodt section page 4 where we were,  
 12 the Item 4, the topic is "Pseudoaddiction-  
 13 Respond With More Opioids." I have it at 32.

14 So taking a step back, do you  
 15 agree that if a patient came to you seeking a  
 16 higher dose of opioid medications, for  
 17 example, "Doctor, my spinal stenosis is  
 18 killing me, I think I need more pain relief,"  
 19 would you automatically conclude that he has  
 20 opioid use disorder, or would you further  
 21 investigate?

22 MR. ARBITBLIT: Object to form.

23 Incomplete hypothetical.

24 THE WITNESS: Your question  
 25 suggests that there are only two

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1 choices there, that either that's a  
 2 legitimate reason to go up or he has  
 3 opioid use disorder. I don't think  
 4 that's how I would conceptualize that  
 5 situation.

6 I think a patient could come in  
 7 and say, "Doctor, I need more opioids  
 8 because my pain is unbearable," and  
 9 that that would not necessarily imply  
 10 that that individual has opioid use  
 11 disorder.

12 On the other hand, that also  
 13 isn't indication to go up on the  
 14 opioids since there's no reliable  
 15 evidence that increasing the dose or  
 16 even using opioids in the first place  
 17 works for chronic pain and the risk  
 18 factors go up with dose and duration.

19 (Lembke Exhibit 15 marked for  
 20 identification.)

21 QUESTIONS BY MR. TSAI:

22 Q. If we could look at the next  
 23 exhibit. This is the document that you cited  
 24 for this characterization.

25 And I would like to direct

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1 you -- this is MNK-T1\_1279950.

2 And it was produced in native,  
 3 so I'll ask you to turn to the internal  
 4 slide 45.

5 Do you see that?

6 Do you agree that on this slide  
 7 that you cited in your report, it doesn't  
 8 actually say "Pseudoaddiction-Respond With  
 9 More Opioids," correct?

10 MR. ARBITBLIT: Object to form.

11 THE WITNESS: You're referring  
 12 to the heading? You're referring to  
 13 my heading there?

14 QUESTIONS BY MR. TSAI:

15 Q. You referenced Slide Number 45?

16 A. Uh-huh.

17 Q. And you referenced that as a  
 18 misrepresentation, which you characterize as  
 19 "Pseudoaddiction-Respond With More Opioids."

20 Do you agree that what you  
 21 referenced doesn't actually say that?

22 MR. ARBITBLIT: Object to form.

23 THE WITNESS: So that's a  
 24 heading that "Pseudoaddiction-Respond  
 25 With More Opioids," is in bold

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1 letters. It's the heading to  
 2 introduce the misrepresentation.  
 3 That's not in quotes, so it's not an  
 4 error.

5 QUESTIONS BY MR. TSAI:

6 Q. Do you have any basis to say  
 7 that Mallinckrodt ever used the term  
 8 "pseudoaddiction" in connection with one of  
 9 its own products specifically?

10 MR. ARBITBLIT: Object to form.

11 THE WITNESS: This example here  
 12 is from a Train-the-Trainer event that  
 13 Mallinckrodt put on to educate a cadre  
 14 of speakers who would again go out and  
 15 disseminate the concept of  
 16 pseudoaddiction more broadly among  
 17 physicians in the United States. It  
 18 doesn't matter that they didn't  
 19 specifically mention their product.

20 They were promoting this  
 21 misrepresentation, which changed the  
 22 way that physicians prescribed opioids  
 23 which promoted their product.

24 QUESTIONS BY MR. TSAI:

25 Q. Can you identify any

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1 Mallinckrodt product that the company  
 2 promoted using the term "pseudoaddiction"?  
 3 MR. ARBITBLIT: Object to form.  
 4 THE WITNESS: I feel like I  
 5 answered that question.

6 QUESTIONS BY MR. TSAI:

7 Q. I haven't heard it, the name of  
 8 a product; is that correct?

9 MR. ARBITBLIT: Object to form.  
 10 Argumentative.

11 THE WITNESS: This reference  
 12 here comes from something called  
 13 Exalgo REMS and CARES Alliance  
 14 Train-the-Trainer, CARES Alliance  
 15 education module. So Exalgo, which is  
 16 one of Mallinckrodt's products, is in  
 17 the heading of this Train-the-Trainer  
 18 event.

19 QUESTIONS BY MR. TSAI:

20 Q. Do you agree that there are  
 21 indicators of addiction that are more  
 22 indicative of addiction compared to others?

23 MR. ARBITBLIT: Object to form.

24 QUESTIONS BY MR. TSAI:

25 Q. As set forth in this slide?

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1 MR. ARBITBLIT: Object to the  
 2 form.  
 3 THE WITNESS: I believe that  
 4 the diagnosis of addiction shouldn't  
 5 be made on just one behavior. It has  
 6 to be a 360-degree view of all of the  
 7 circumstances involved.

8 QUESTIONS BY MR. TSAI:

9 Q. So stealing money to obtain  
 10 drugs, you would agree, is a behavior more  
 11 indicative of potential addiction than using  
 12 more opioids than recommended?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: Not necessarily.

15 Given that individual's  
 16 circumstance, stealing money to obtain  
 17 drugs or using more than recommended,  
 18 they may have equal severity of  
 19 disease. It really depends.

20 Because of the myth perpetrated  
 21 by the defendants that no dose is too  
 22 high, I have seen many cases of  
 23 patients who were receiving many more  
 24 morphine milligram equivalents daily  
 25 directly from their prescriber than

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1 patients who are getting illicit  
 2 opioids on the street.  
 3 So for several generations it  
 4 wasn't necessary to go out and find a  
 5 dealer or to steal money or any of  
 6 these other listings in order to be  
 7 severely addicted because you could  
 8 get your opioids directly from a  
 9 well-intentioned doctor who was taught  
 10 that no dose is too high.

11 QUESTIONS BY MR. TSAI:

12 Q. So the differential diagnosis  
 13 of whether a particular individual has true  
 14 addiction under DSM-IV, DSM-V, what have you,  
 15 versus needing more pain relief legitimately,  
 16 does depend on individual circumstances, you  
 17 would agree?

18 MR. ARBITBLIT: Object to form.

19 THE WITNESS: I agree that all  
 20 of the information needs to be taken  
 21 into account with the caveat that  
 22 several generations of physicians have  
 23 been miseducated as to the evidence.

24 (Lembke Exhibit 16 marked for  
 25 identification.)

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1 QUESTIONS BY MR. TSAI:

2 Q. And you mentioned dose. If you  
 3 could look at the next exhibit in order.

4 And this is still on page 4 of  
 5 the Mallinckrodt section of Appendix I.B,  
 6 Number 3 heading is the topic of "No Dose is  
 7 Too High," and you cited MNK-T1\_626241  
 8 through 626269, specifically at page 6262 and  
 9 once the exhibit is marked, if you could turn  
 10 to that.

11 A. What page number in the  
 12 exhibit?

13 Q. 6262 is the ending.

14 A. It only goes up to -- oh.

15 Q. The next exhibit.

16 A. I see. I'm sorry. 626257?

17 Q. 626262.

18 A. Oh, okay.

19 Q. And once again, just for  
 20 clarity, the heading that you have in your  
 21 report, "No Dose is Too High," it doesn't  
 22 actually say that in the page that you've  
 23 cited in Mallinckrodt's document; do you  
 24 agree?

25 MR. ARBITBLIT: Object to form.

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1                   THE WITNESS: I don't see those  
 2 exact words, but equivalent words,  
 3 quote, "Be sure to continue to titrate  
 4 upwards until an effective dose is  
 5 reached. This is essential to overall  
 6 patient success," unquote.

7 QUESTIONS BY MR. TSAI:

8                   Q.     Do you have any basis to say  
 9 that Mallinckrodt ever caused any doctor in  
 10 Cuyahoga and Summit Counties to overtreat  
 11 to such a level that led to an adverse event?

12                  MR. ARBITBLIT: Object to form.

13                  THE WITNESS: I believe that  
 14 doctors in the Summit and Cuyahoga  
 15 County, like the rest of the nation,  
 16 were taught that no dose is too high,  
 17 such that they increased their doses  
 18 of their patients with good  
 19 intentions, putting those patients at  
 20 imminent risk for overdose and  
 21 addiction.

22                  And we know that Cuyahoga and  
 23 Summit Counties have not been spared  
 24 the opioid epidemic, that there are if  
 25 not equal, even worse rates of opioid

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1                   addiction and overdose in the state of  
 2 Ohio and in those counties.

3 QUESTIONS BY MR. TSAI:

4                   Q.     Can you name a single specific  
 5 doctor or patient that fits that scenario  
 6 that you've just posited in Cuyahoga --

7                   MR. ARBITBLIT: Object to form.

8 QUESTIONS BY MR. TSAI:

9                   Q.     -- and Summit Counties?

10                  MR. ARBITBLIT: Object to form.

11                  THE WITNESS: I can't name  
 12 specifics, but given the death  
 13 rates...

14 QUESTIONS BY MR. TSAI:

15                  Q.     So in your report, you talk  
 16 about an article that talks about a 1 percent  
 17 rate of addiction.

18                  Can you identify any instance  
 19 where Mallinckrodt used the phrase "less than  
 20 1 percent get addicted"?

21                  A.     Mallinckrodt has used terms  
 22 such as "rarely" and "uncommon" to describe  
 23 the risk of addiction in patients treated  
 24 with opioids for chronic pain.

25                  I don't see the specific

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1 reference to less than 1 percent, but they  
 2 used equivalent phrases.

3                  Q.     And my last question: Do you  
 4 have any basis to say that when doctors in  
 5 Cuyahoga or Summit County heard the  
 6 qualitative adjectives "low" or "rarely,"  
 7 that they had any specific number in mind?

8                  MR. ARBITBLIT: Object to form.

9                  THE WITNESS: The messaging  
 10 that was dominant in the '90s and  
 11 early aughts, all over the United  
 12 States, was that the risk of addiction  
 13 is rare, uncommon, less than  
 14 1 percent, very unlikely in patients  
 15 treated with opioids for a chronic  
 16 pain condition.

17                  And so, hence, I believe that  
 18 prescribers in Cuyahoga and Summit  
 19 Counties were also led to believe that  
 20 that was the case, even though that is  
 21 a misrepresentation of the evidence.

22 QUESTIONS BY MR. TSAI:

23                  Q.     Did you conduct any survey or  
 24 any analysis of any doctors in Cuyahoga and  
 25 Summit Counties regarding what number they

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1 associate, say, with the adjective "low"?

2                   MR. ARBITBLIT: Object to form.

3                  THE WITNESS: I didn't do a  
 4 survey on the adjective "low" in  
 5 Summit or Cuyahoga Counties.

6                  MR. TSAI: Thank you.  
 7 Reserving all rights, I'll pass the  
 8 witness at this time. We should go  
 9 off the record.

10                 VIDEOGRAPHER: Okay. We're now  
 11 going off the record, and the time is  
 12 2:20 p.m.

13                 (Off the record at 2:20 p.m.)  
 14                 VIDEOGRAPHER: We are now going  
 15 back on the record, and the time is  
 16 2:22 p.m.

17                 CROSS-EXAMINATION

18 QUESTIONS BY MR. LAVELLE:

19                  Q.     Good afternoon, Doctor. My  
 20 name is John Lavelle, I'm an attorney at  
 21 Morgan Lewis, and I'm representing Rite Aid  
 22 of Maryland doing business as Mid Atlantic  
 23 Distribution Center.

24                  Are you aware that pharmacies  
 25 have been sued as defendants in this

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1 litigation?

2 A. Yes, I am.

3 Q. Okay. Now, when you were

4 retained as an expert in the case in January

5 of 2018, the pharmacies were not defendants;

6 is that right?

7 A. I was not aware of that.

8 Q. Okay. When did you become

9 aware that pharmacies were defendants in the

10 litigation?

11 A. When I read the complaint.

12 Q. All right. You must have read

13 the first amended complaint, because they

14 weren't in the original complaint, right?

15 So when did you read the

16 complaint that had the pharmacies as

17 defendants?

18 A. About two weeks ago.

19 Q. Okay. In preparation for

20 today's deposition.

21 A. That's right.

22 Q. So I'm going to be asking you

23 some questions on behalf of a group of

24 defendants who we refer to as the retail

25 pharmacy defendants. So let me just name

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1 them for you and ask you whether you're aware

2 that they are defendants. So the first one

3 is the client I am representing, Rite Aid.

4 You're aware that Rite Aid is a

5 defendant in the case?

6 A. Yes.

7 Q. Other retail pharmacy

8 defendants include Walgreens. Are you aware

9 that they're a defendant in the case?

10 A. Yes.

11 Q. Are you aware that Walmart is a

12 defendant in the litigation?

13 A. Yes.

14 Q. You're aware that CVS is a

15 defendant in the litigation?

16 A. Yes.

17 Q. Are you aware that Giant Eagle

18 is a defendant in the litigation?

19 A. Yes.

20 Q. Okay. And you became aware of

21 all of those as defendants as of two weeks

22 ago; is that right?

23 A. That's correct.

24 Q. Now, you prepared your report

25 in this matter as of March 25, 2019; is that

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1 right?

2 A. Yes.

3 Q. I'm just looking at the cover

4 of your report, and that's the date that you

5 have on it, right?

6 A. Well, I would say that my

7 report is based on the research that I did

8 prior to being retained by counsel, as well

9 as the ongoing and additional research that I

10 did beginning in the spring of 2019 until the

11 finalized and submitted report.

12 Q. Understood.

13 So the finalized and submitted

14 report was dated March 25, 2019; is that

15 correct, Doctor?

16 A. I think that's the date, yes.

17 Q. Were you aware when you

18 finalized this report that all those retail

19 pharmacy defendants were defendants in the

20 litigation?

21 A. I knew that pharmacies were

22 defendants in the litigation, along with

23 distributors and opioid manufacturers. I

24 wasn't aware of the specific pharmacies that

25 were named.

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1 Q. All right. So I'm just trying

2 to get the timing --

3 A. Yes.

4 Q. -- the timing right, because I

5 think you said earlier, and I don't want to

6 misrepresent it, but you learned about the

7 specific pharmacies about two weeks ago when

8 you were preparing for the deposition?

9 A. Yes. But I knew that

10 pharmacies were named much earlier on.

11 Q. I see.

12 All right. So --

13 A. And I'm sorry.

14 Q. Yes.

15 A. I also read an earlier version

16 of the complaint much earlier than two weeks

17 ago. I can't remember the exact date that I

18 read the earlier version of the complaint.

19 Q. Do you recall whether that

20 earlier version of the complaint had

21 pharmacies as defendants in the case?

22 A. I believe that it did.

23 Q. All right. Are you aware of

24 what the plaintiffs' claims are against the

25 retail pharmacies in this litigation?

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1           A.     I haven't been asked to express  
 2       an opinion on that. I understand that there  
 3       will be other expert witnesses who will  
 4       testify in that regard, but broadly speaking,  
 5       based on my understanding of the overall  
 6       problem, as well as my reading of the  
 7       complaint, pharmacies are accused of not  
 8       acting or turning the other cheek when it was  
 9       patently obvious that they were disseminating  
 10      prescription opioid pain relievers to  
 11      individuals who were struggling with opioid  
 12      addiction and at risk because of opioids.

13           Q.     So just to break that down.  
 14      I'll have a couple follow-ups for you on  
 15      that.

16                  Do you know whether these  
 17      retail pharmacy chains have been sued as  
 18      distributors or as dispensers or both?

19                  MR. ARBITBLIT: Object to form.

20                  THE WITNESS: My understanding,  
 21      based on what's in the public domain,  
 22      as well as my reading of the  
 23      complaint, is that there are  
 24      essentially three groups of  
 25      defendants: There are opioid

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1           manufacturers; there are opioid  
 2       distributors; and there are opioid  
 3       pharmacies, some of which act also as  
 4       dispensers.

5           QUESTIONS BY MR. LAVELLE:

6           Q.     All right. So you believe, as  
 7       you sit here today, that there are claims  
 8       against the pharmacies as dispensers?

9                  MR. ARBITBLIT: Object to form.

10          QUESTIONS BY MR. LAVELLE:

11           Q.     Is that what you believe?

12           A.     Could you define "dispensers"?

13           Q.     Yes.

14                  Someone who fills prescriptions  
 15      for a medical product such as an opioid.

16           A.     Yes, that's my understanding.

17           Q.     Okay. Now, I think you said in  
 18      response to a question a couple moments ago  
 19      that you have not formed any opinions with  
 20      respect to the pharmacies; is that correct?

21           A.     I was not asked to opine with  
 22      respect to pharmacies, but broadly I agree  
 23      with the complaint that all of those entities  
 24      comprise what I have called the  
 25      pharmaceutical opioid industry, and all bear

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1       some responsibility.

2           Q.     All right. So we're going to  
 3      need to get into that in a little more detail  
 4      because that was one question I had for you,  
 5      is you used the term in this report  
 6      "pharmaceutical opioid industry," but you  
 7      haven't defined what that -- what you mean by  
 8      that.

9                  Can you explain what you mean  
 10     by that and who was included in that?

11           A.     The pharmaceutical opioid  
 12      industry, as used in my report, refers to the  
 13      named opioid manufacturers, the named opioid  
 14      distributors, and the named opioid dispensing  
 15      pharmacies.

16           Q.     All right. Are you aware of  
 17      any marketing of opioids that was done by any  
 18      of the retail chain pharmacies?

19           A.     No, I am not.

20           Q.     And, in fact, you do not  
 21      reference any marketing of opioids by any of  
 22      the retail chain pharmacies in your report;  
 23      isn't that correct?

24           A.     That is correct.

25           Q.     So when you have talked during

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1       your deposition today and when you talk in  
 2      your report about marketing by defendants or  
 3      marketing by the pharmaceutical opioid  
 4      industry, you're not referring to any of the  
 5      retail chain pharmacies, right?

6           A.     That's correct.

7           Q.     You're not referring to Rite  
 8      Aid; you're not referring to Walmart; you're  
 9      not referring to CVS, Walgreens or Giant  
 10     Eagle. Is that correct?

11           A.     That's correct.

12           Q.     Did you review any marketing  
 13      materials from any of those entities?

14           A.     I did not.

15           Q.     To the best of your knowledge,  
 16      did any of those entities actually engage in  
 17      any marketing of opioids?

18           A.     Not to my knowledge.

19           Q.     Now, would you agree with me  
 20      that pharmacists have a duty to fulfill  
 21      prescriptions that are presented to them when  
 22      there's a valid doctor-patient relationship?

23                  MR. ARBITBLIT: Object to form.

24                  THE WITNESS: Pharmacists have  
 25      many duties, one of which includes

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1 filling prescriptions, but they also  
 2 have a duty to keep patients safe and  
 3 when they see warning signs about a  
 4 patient asking for certain types of  
 5 medications, be it the type of  
 6 medication or the mixing of that  
 7 medication with another dangerous  
 8 medication or the quantity of that  
 9 medication, they have a duty to warn  
 10 the patient and potentially also  
 11 contact the provider and warn the  
 12 provider.

13 And if it's on a large-enough  
 14 scale, I would think that they would  
 15 have a duty to also alert the  
 16 distributors, the FDA, anybody else  
 17 who's involved in making sure that  
 18 patient stays safe vis-à-vis these  
 19 medications.

20 QUESTIONS BY MR. LAVELLE:

21 Q. Now, you do not have that --  
 22 you have not expressed that opinion in your  
 23 report; is that correct?

24 A. That's correct.

25 Q. You weren't asked to offer an

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1 opinion on that; is that correct?

2 A. That's correct.

3 Q. And you don't have that opinion  
 4 to a reasonable degree of medical certainty;  
 5 is that correct?

6 MR. ARBITBLIT: Object to form.

7 THE WITNESS: Well, I have that  
 8 opinion, and I'm pretty certain about  
 9 it, but I wasn't asked to opine on it  
 10 in my report.

11 QUESTIONS BY MR. LAVELLE:

12 Q. Okay. If you believe that  
 13 doctors were duped into increasing opioid  
 14 prescriptions, do you believe pharmacists  
 15 were also duped?

16 A. I think it's possible that on  
 17 an individual basis some pharmacists were  
 18 also not aware of the dangers with opioids.  
 19 It's possible.

20 Q. It's possible, but you're not  
 21 certain?

22 A. That's right.  
 23 Mainly because I'm not as  
 24 familiar with pharmacy training as I am with  
 25 physician training.

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1 Q. What knowledge do you have  
 2 about pharmacy training?

3 A. I know that they have a  
 4 certification -- they have schooling, a  
 5 certification process, but I don't know a  
 6 whole lot more than that.

7 Q. Okay. You're not a pharmacist?

8 A. No. And I haven't studied what  
 9 pharmacists go through.

10 Q. And you wouldn't hold yourself  
 11 out as having expertise with respect to  
 12 pharmacy?

13 A. That's correct.

14 Q. A second here. Do you have any  
 15 knowledge as we sit here today concerning the  
 16 distribution activities of any of those  
 17 retail pharmacy chains that I mentioned  
 18 earlier?

19 A. I have some knowledge based on  
 20 what's in the public domain about  
 21 distribution activities more broadly of  
 22 opioid pain pills, specifically the influx of  
 23 very large amounts of opioid pain pills in  
 24 small communities that could not possibly be  
 25 justified based on the need for analgesia in

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1 that community.

2 Q. Do you know, as you're sitting  
 3 here today, whether any of the retail chain  
 4 pharmacies I mentioned earlier actually  
 5 distributed opioids?

6 A. I have not been asked to opine  
 7 on that.

8 Q. And you don't know which  
 9 opioids they distributed, if any; is that  
 10 right?

11 A. That's right.

12 MR. LAVELLE: Okay. I'm going  
 13 to stop there. Thank you, Doctor.

14 THE WITNESS: You're welcome.

15 VIDEOGRAPHER: Okay. We're now  
 16 going off the record, and the time is  
 17 2:33 p.m.

18 (Off the record at 2:33 p.m.)

19 VIDEOGRAPHER: We are now going  
 20 back on the record, and the time is  
 21 2:35 p.m.

22 CROSS-EXAMINATION

23 QUESTIONS BY MR. MOONEY:

24 Q. Good afternoon. My name is  
 25 Matt Mooney. I am an attorney with the law

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1 firm of Williams & Connolly.  
 2 You said you read the  
 3 complaint -- the complaints in this case, at  
 4 least two weeks ago, possibly before; is that  
 5 right?  
 6 A. Yes.  
 7 Q. And I believe you said that  
 8 you're aware of the role of distributors in  
 9 this case; is that correct?  
 10 A. That's correct.  
 11 Q. Which distributors have been  
 12 named as defendants in this litigation?  
 13 A. Cardinal, McKesson,  
 14 AmerisourceBergen are the ones that I recall.  
 15 Q. Okay. Do you know if any other  
 16 distributors were named as defendants in this  
 17 litigation?  
 18 A. I can't recall.  
 19 Q. Prescription Supply, have you  
 20 ever heard of that company?  
 21 A. No.  
 22 Q. Do you know if they're named as  
 23 a defendant in this case?  
 24 A. I don't recall.  
 25 Q. How about a company called

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1 Henry Schein, do you know if they're a  
 2 defendant in this case?  
 3 A. I don't recall.  
 4 Q. Miami-Lukens?  
 5 A. I don't recall.  
 6 Q. Anda?  
 7 A. I don't recall.  
 8 Q. Earlier today you said that you  
 9 acknowledged the distributors' contribution  
 10 to the opioid epidemic; is that right?  
 11 A. Yes.  
 12 Q. Okay. Are you prepared to  
 13 offer an opinion in this litigation  
 14 concerning the contribution of any  
 15 distributor to the opioid epidemic?  
 16 A. It's my opinion -- it's my  
 17 understanding that other expert witnesses  
 18 will be offering testimony on distributors.  
 19 I've not been asked to offer testimony on  
 20 that.  
 21 Q. Okay. And so when you  
 22 referenced the pharmaceutical opioid industry  
 23 in your report, are distributor defendants  
 24 included in that insofar as -- strike all  
 25 that.

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1 You mentioned the  
 2 pharmaceutical opioid industry in your  
 3 report, and you told Mr. Lavelle that as you  
 4 define that term, it includes manufacturers,  
 5 distributors and pharmacies; is that right?  
 6 A. That's right.  
 7 Q. When you reference misleading  
 8 or false marketing material and attribute it  
 9 to the pharmaceutical opioid industry in your  
 10 report, are you referring to the distributors  
 11 that have been named as defendants in this  
 12 case?  
 13 A. No.  
 14 Q. And in preparing your report,  
 15 did you consider any documents that were  
 16 produced by a distributor that is named as a  
 17 defendant in this case?  
 18 A. No.  
 19 Q. Do you have any training or  
 20 expertise in supply chain management?  
 21 A. No.  
 22 Q. Do you have any training or  
 23 expertise in the distribution of controlled  
 24 substances?  
 25 A. No.

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1 Q. Do you have any training or  
 2 experience in suspicious order monitoring for  
 3 controlled substances?  
 4 A. No.  
 5 Q. Do you have any training or  
 6 expertise in a distributor's legal or  
 7 regulatory responsibilities concerning the  
 8 distribution of controlled substances?  
 9 A. No.  
 10 Q. Do you have your report in  
 11 front of you?  
 12 A. I do.  
 13 Q. Okay. If you don't mind  
 14 turning to page 82 of your report.  
 15 Are you there?  
 16 A. Yes.  
 17 Q. Okay. Do you see where you  
 18 say, "In the case of prescription opioids,  
 19 factors relevant to that epidemic have been  
 20 addressed throughout this report and are  
 21 summarized as follows."  
 22 Do you see where it says that  
 23 in your report?  
 24 A. Yes.  
 25 Q. And then one of the bullets

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1 below says, "An efficient distributor supply  
 2 chain made prescription opioids available on  
 3 a mass scale to large numbers of people in  
 4 rural and remote settings expanding both the  
 5 elicit and illicit drug market and sets this  
 6 opioid epidemic apart from prior epidemics  
 7 and other drug epidemics."

8                 Did I read that correctly?

9                 A.       Yes.

10          Q.       And that paragraph doesn't have  
 11 a footnote identifying any documents that  
 12 support that position; is that correct?

13          A.       That's correct.

14          Q.       Okay. Where else in your  
 15 report did you address the fact that an  
 16 efficient distributor supply chain made  
 17 prescription opioids available in a mass  
 18 scale?

19          A.       That's the only place.

20          Q.       Okay. And what do you mean by  
 21 "an efficient distributor supply chain"?

22          A.       By that I mean the fact that  
 23 very easily large quantities of opioid pain  
 24 pills could be disseminated all across the  
 25 country, even in remote and rural regions,

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1 putting those individuals at higher risk  
 2 because access to addictive substances is one  
 3 of the major risk factors for becoming  
 4 addicted.

5                 Q.       Okay. And are you going to be  
 6 offering an opinion in this litigation that  
 7 an efficient distributor supply chain made  
 8 prescription opioids available on a mass  
 9 scale?

10          A.       It's in my report, so I will be  
 11 offering that opinion.

12          Q.       Okay. And so what did you --  
 13 what documents did you rely upon to determine  
 14 that an efficient distributor supply chain  
 15 made prescription opioids available on a mass  
 16 scale to large numbers of people, expanding  
 17 both the elicit and illicit drug market?

18          A.       I based that on the  
 19 epidemiology of the opioid epidemic and the  
 20 fact that unlike other drug crises in our  
 21 history which typically have been isolated to  
 22 specific geographical regions, what we see  
 23 with the opioid epidemic is a dissemination  
 24 across all states, all counties, and I  
 25 attribute that to this efficient distributor

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1 supply chain.

2                 Q.       Okay. Did you review any  
 3 documents or any distribution data related to  
 4 the distribution of opioids in forming your  
 5 opinion?

6                 A.       No, but I did have access to  
 7 what is in the public domain regarding that.

8                 Q.       And did you review that and  
 9 consider it in forming your opinion in this  
 10 report?

11          A.       Yes.

12          Q.       Okay. And is that -- what data  
 13 did you rely on?

14          A.       I relied on what I read in the  
 15 public domain regarding, for example, small  
 16 towns in rural West Virginia that received  
 17 millions of prescriptions for a town of a  
 18 thousand people. Those aren't exact numbers,  
 19 but just to give a sense of the problem.

20          Q.       So you didn't review any  
 21 specific distribution data related to  
 22 prescription opioids?

23          A.       That's correct.

24          Q.       Okay. Did you conduct any  
 25 analysis of the distribution of opioids to

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1 Summit or Cuyahoga County in order to form an  
 2 opinion in this case?

3                 A.       No.

4                 Q.       And so other than what you have  
 5 read in the public domain about the number of  
 6 prescription pills -- opioid pills that have  
 7 been distributed, have you relied on any  
 8 other information to opine that an efficient  
 9 distributor supply chain made prescription  
 10 opioids available in a mass scale?

11          A.       No.

12          Q.       Another bullet on that page 83.

13          A.       Yeah.

14          Q.       And so this is, again,  
 15 something that -- this is something that you  
 16 write, "In the case of prescription opioids,  
 17 factors relevant to that epidemic have been  
 18 addressed throughout this report and are  
 19 summarized as follows," this is another one  
 20 of the bullets, correct?

21                 And you wrote, "The problem of  
 22 addiction more broadly in society and culture  
 23 today does not negate the significant role of  
 24 opioid manufacturers and distributors in  
 25 causing this epidemic."

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1 Did I read that correctly?  
 2 A. Yes.  
 3 Q. Okay. And I think I understood  
 4 you earlier to say that you're not offering  
 5 an opinion in this case about the conduct of  
 6 any distributor that's been named as a  
 7 defendant in this case; is that right?  
 8 A. Except for what's in my report.  
 9 Q. Okay. So what is your basis  
 10 for determining that the opioid distributors  
 11 played a role in causing the opioid epidemic?  
 12 A. The widespread nature of the  
 13 opioid epidemic.  
 14 Q. And what do you mean by "the  
 15 widespread nature of the opioid epidemic"?  
 16 A. The fact that every region in  
 17 the country has been affected. The fact that  
 18 the risk of opioid addiction and overdose  
 19 death in a given county is directly  
 20 correlated with the amount of prescribing in  
 21 that county.  
 22 Q. Anything else?  
 23 A. No.  
 24 Q. And this paragraph -- or this  
 25 bullet also doesn't have a footnote

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1 identifying any documents on which you relied  
 2 to support your opinion, correct?  
 3 A. That's correct.  
 4 Q. And you didn't consider any  
 5 documents that were produced by the  
 6 distributor defendants in reaching the  
 7 opinion that you have in that bullet,  
 8 correct?  
 9 A. That's correct.  
 10 Q. You haven't done any analysis  
 11 of the distribution patterns of any  
 12 distributor, defendant or not, to reach that  
 13 opinion; is that correct?  
 14 A. That's correct.  
 15 Q. When you mentioned earlier that  
 16 you spoke at Ohio State University, at least  
 17 in April 2018 and February 2019; is that  
 18 right?  
 19 A. Yes.  
 20 Q. Did you tell the audience that  
 21 you had been retained by the plaintiffs in  
 22 this litigation during your talk?  
 23 A. I did not inform the audience  
 24 that in April 2018, but if memory serves, I  
 25 believe I did in February 2019, although I'm

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1 not 100 percent certain.  
 2 Q. Okay. Your report identifies  
 3 information, marketing, that you believe  
 4 was -- promoted misconceptions concerning  
 5 opioids; is that correct?  
 6 A. Yes.  
 7 Q. And your report doesn't  
 8 identify any marketing claims by any of the  
 9 distributor defendants, does it?  
 10 A. No.  
 11 Q. Okay. Are you aware of any  
 12 distributor defendant that has been named in  
 13 this case as having made a false or  
 14 misleading marketing claim regarding opioids?  
 15 A. I didn't review that material.  
 16 Q. Is it your opinion that the  
 17 distributor defendants were aware that  
 18 marketing material concerning the safety and  
 19 efficacy of opioids contained misleading or  
 20 false information?  
 21 A. My guess is they were probably  
 22 aware, but I don't have anything specific to  
 23 base that on.  
 24 Q. Okay. And so when you say your  
 25 "guess is that they were probably aware,"

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1 you're not relying on any expertise to say --  
 2 to reach that conclusion, correct?  
 3 A. Well, I mean, my expertise is  
 4 my research of the opioid epidemic more  
 5 broadly, and my -- I agree with the complaint  
 6 that this was a kind of collusion or a  
 7 synchronicity among all of the defendants.  
 8 Q. Have you reviewed any documents  
 9 that have been produced in this case that  
 10 show that there is collusion or a  
 11 synchronicity between the defendants in this  
 12 case?  
 13 A. I wasn't asked to review those  
 14 documents. I have not reviewed those  
 15 documents.  
 16 Q. So that's just your opinion?  
 17 A. Yes.  
 18 Q. But it's not based on anything  
 19 you've seen or reviewed for the purposes of  
 20 this case?  
 21 A. That's correct.  
 22 Q. Okay. You described that there  
 23 was a paradigm shift in the prescribing of  
 24 opioids; is that right?  
 25 A. Yes.

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1 Q. And I understand that you  
 2 believe that that paradigm shift was due to  
 3 certain false or misleading statements that  
 4 were made; is that right?

5 A. That's correct.

6 Q. Okay. Setting aside for a  
 7 minute the reasons for the paradigm shift, do  
 8 you agree that because of the paradigm shift  
 9 it was a generally accepted medical practice  
 10 to prescribe opioid medications for the  
 11 treatment of chronic noncancer pain?

12 A. Yes.

13 Q. And for the treatment of acute  
 14 pain?

15 A. I think for the treatment of  
 16 acute pain, it was already an established  
 17 practice. It was the transition to using  
 18 opioids for minor pain conditions and using  
 19 opioids in high doses long-term for chronic  
 20 pain that was really the departure from past  
 21 practice and also from the evidence.

22 Q. Other than documents that the  
 23 distributor defendants produced in this  
 24 litigation, did you review any materials and  
 25 consider them in forming your report that in

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1 order to reach the opinions that you purport  
 2 to have regarding the efficient supply chain  
 3 and the distributor -- the opioid --  
 4 distributors' role in causing an opioid  
 5 epidemic?

6 MR. ARBITBLIT: Objection.  
 7 Argumentative.

8 THE WITNESS: No.

9 QUESTIONS BY MR. MOONEY:

10 Q. Okay. And so other than the  
 11 public reporting that you've seen about the  
 12 number of pills, you don't have any other  
 13 basis to opine that opioid distributors  
 14 played a role in causing an opioid epidemic?

15 MR. ARBITBLIT: Object to form.  
 16 Misstates the record.

17 THE WITNESS: Yeah, I was not  
 18 asked to give an opinion on that. I  
 19 understand that other experts will  
 20 give an opinion on that.

21 QUESTIONS BY MR. MOONEY:

22 Q. Okay. So you aren't going to  
 23 get -- you aren't going to state that opinion  
 24 at trial then; is that right?

25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: Well, if somebody  
 2 asks me my opinion, I will state  
 3 what's in my report.

4 QUESTIONS BY MR. MOONEY:

5 Q. Okay. And what will be the  
 6 basis for the opinion other than the public  
 7 reporting that you've identified?

8 A. And the information that I read  
 9 in the complaint.

10 Q. Okay. And you understand that  
 11 the allegations in a complaint are not  
 12 necessarily proven as true until the evidence  
 13 introduced at trial supports them; is that  
 14 right?

15 A. Okay. Yes.

16 MR. MOONEY: Okay. Can we go  
 17 off the record for a moment?

18 VIDEOGRAPHER: Okay. We're now  
 19 going off the record, and the time is  
 20 2:51 p.m.

21 (Off the record at 2:51 p.m.)

22 VIDEOGRAPHER: We are now going  
 23 back on the record, and the time is  
 24 3:03 p.m.

25 (Lembke Exhibit 17 marked for

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1 identification.)

2 CROSS-EXAMINATION

3 QUESTIONS BY MR. EHSAN:

4 Q. Good afternoon, Dr. Lembke. My  
 5 name is Houman Ehsan, and I represent the  
 6 Janssen defendants in this litigation.  
 7 Doctor, do you know which  
 8 prescription opioids, if any, Janssen  
 9 manufactures or manufactured?

10 A. I'm sorry? I didn't hear that.

11 Q. Do you know -- sure.

12 Do you know which opioid  
 13 medications Janssen manufactures or  
 14 manufactured?

15 A. Opana ER and Percocet.

16 Q. Thank you, Doctor.

17 I've handed you what's been  
 18 marked Exhibit 17 to your report, which is --  
 19 or Exhibit 17 to this deposition, which is  
 20 Appendix I.C of your report, and it  
 21 specifically reference Janssen's misleading  
 22 messages; is that correct?

23 A. Yes.

24 Q. Focusing your attention on the  
 25 bottom of the page, A 3, you note that there

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1 is a document that describes how opioids  
 2 improve function and quality of life, and you  
 3 reference a particular Bates number that ends  
 4 in 573.

5 Do you see that?

6 A. Yes.

7 Q. And is it your opinion, Doctor,  
 8 that this was a misleading message that  
 9 Janssen disseminated?

10 A. Yes.

11 (Lembke Exhibit 18 marked for  
 12 identification.)

13 QUESTIONS BY MR. EHSAN:

14 Q. Doctor, I'm going to hand you  
 15 what's going to be marked as Exhibit 18.

16 And, Doctor, please note that  
 17 the Bates stamp on this document ends in 5 --  
 18 or ends in 809573, which is the same Bates  
 19 stamp as what's referenced in Item 3,  
 20 Exhibit 17, we just talked about.

21 Do you see that?

22 If you go back to the first  
 23 page of Exhibit 17, the last item on that  
 24 page --

25 A. Yes.

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1 Q. -- is a document from 573 to  
 2 575, and that happens to be the same Bates  
 3 range for this document; is that correct?

4 A. Yes.

5 Q. I just want to take -- bring  
 6 your attention to the very top left-hand side  
 7 of this document.

8 Do you see how it states,  
 9 "Draft 7/16/02"?

10 A. Yes.

11 Q. At the time you reviewed this  
 12 document, did you appreciate that it was a  
 13 draft document?

14 A. I did not.

15 Q. Did you believe that this  
 16 document was, in fact, disseminated to anyone  
 17 in particular?

18 A. I'm not sure I knew for sure  
 19 whether it had been disseminated.

20 Q. Sitting here today, Doctor,  
 21 would you agree that you don't have a basis  
 22 to opine to a reasonable degree of medical  
 23 certainty that this document, labeled with a  
 24 draft notation, was actually disseminated to  
 25 any doctor in Cuyahoga or Summit County,

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1 correct?  
 2 A. If it wasn't disseminated,  
 3 period, then it wasn't likely disseminated to  
 4 doctors in Cuyahoga and Summit Counties.

5 Q. Well, do you have an opinion as  
 6 to whether or not a draft document would be  
 7 disseminated to doctors in the community?

8 A. Well, just because it says  
 9 "draft" on it isn't proof to me that it  
 10 wasn't disseminated.

11 Q. Well, would you agree that you  
 12 cannot opine to a reasonable degree of  
 13 medical certainty that the document wasn't  
 14 altered or changed or edited before it was  
 15 disseminated, if it was, in fact,  
 16 disseminated?

17 A. I can't speak to that.

18 What's salient to me, however,  
 19 is that Janssen was reprimanded by the FDA  
 20 for this document, and if it wasn't  
 21 disseminated, it's likely that without  
 22 reprimand it would have been disseminated  
 23 because it's very similar to the types of  
 24 messaging that were otherwise disseminated.

25 Q. Again, you cite a draft

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1 document and you believed the FDA reprimanded  
 2 Janssen for this draft document; is that  
 3 correct?

4 MR. ARBITBLIT: Object to form.  
 5 Misstates.

6 THE WITNESS: Yes, I do believe  
 7 that the FDA reprimanded Janssen for  
 8 this document.

9 (Lembke Exhibit 19 marked for  
 10 identification.)

11 QUESTIONS BY MR. EHSAN:

12 Q. Thank you, Doctor. You can put  
 13 that aside.

14 I want to hand you a two-part  
 15 document. And we will be marking that as --  
 16 I believe that's 19.

17 And I apologize for the fact  
 18 that it's a two-piecer, but it was produced  
 19 natively, so the first page actually has the  
 20 Bates stamp and the native document is  
 21 printed behind.

22 I want to focus your attention  
 23 on page 3 of Exhibit 17, which is your  
 24 Exhibit 1.C.

25 Let me know when you're there.

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1 A. Page 3 of my report?  
 2 Q. That's correct.  
 3 A. Okay.  
 4 Q. Let me know when you're there.  
 5 A. I'm there.  
 6 Q. The second bullet point on that  
 7 page references speakers' notes from a  
 8 Janssen sales training presentation site to  
 9 Joranson 2000 that -- to state that  
 10 "Investigators concluded that the trend of  
 11 increasing medical use of opioid analgesics  
 12 to treat pain does not appear to contribute  
 13 to increases in health consequences of opioid  
 14 abuse, period."

15 Did I read that correctly,  
 16 Doctor?

17 A. The second bullet point on  
 18 page 3? Yes, you did.

19 Q. And the reference you give or  
 20 the Bates stamp reference you give for this  
 21 document is JAN-MS-0032787, correct?

22 A. Yes.

23 Q. If you look at the first half  
 24 of what's been handed to you as Exhibit 19,  
 25 do you see that that document bears the same

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1 Bates stamp, JAN-MS-0032787?  
 2 A. I'm not --  
 3 Q. You have to look at the bottom  
 4 of this document.

5 A. Oh, I see.  
 6 Q. Because it was produced  
 7 natively unfortunately it doesn't have Bate  
 8 stamps on the actual document.

9 A. Yes.

10 Q. Okay. And I'll represent to  
 11 you that the natively produced document is  
 12 the second half of that Exhibit 19 that I've  
 13 handed to you.

14 I just want to draw your  
 15 attention to the first page of the document.

16 Do you see that this is, in  
 17 fact, a Duragesic PowerPoint presentation?

18 A. Yes.

19 Q. And do you see at the bottom  
 20 there's a little note "For PriCara training  
 21 use only. Do not duplicate, modify,  
 22 distribute or use this item when detailing."

23 Do you see that?

24 A. Yes.

25 Q. Do you understand what the term

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1 "detailing" means?  
 2 A. I do.  
 3 Q. And what is your understanding  
 4 of that term?  
 5 A. It's the phenomenon of  
 6 representatives from pharmaceutical companies  
 7 going to -- directly to prescribers to,  
 8 quote/unquote, educate them about their drug.  
 9 Q. So when the statement of this  
 10 document bears a stamp that you are not to  
 11 duplicate, modify, distribute or use this  
 12 item when detailing, would that suggest to  
 13 you, Doctor, that it should not be -- should  
 14 not have been used by pharmaceutical  
 15 representatives in their interactions with  
 16 physicians?

17 MR. ARBITBLIT: Object to form.  
 18 Misleading.

19 THE WITNESS: I'm quite  
 20 doubtful that that small print at the  
 21 bottom of this page had a substantial  
 22 impact on the messaging that  
 23 representatives from Janssen used when  
 24 they went to detail prescribers or  
 25 other trainees of Janssen messaging.

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1 The overall messaging is  
 2 consistent what I have in my report  
 3 that the benefits of opioids were  
 4 overstated and the risks were  
 5 understated, and this is an example of  
 6 that.

7 MR. EHSAN: I'll move to strike  
 8 as nonresponsive.

9 QUESTIONS BY MR. EHSAN:

10 Q. Doctor, my question was a  
 11 little bit more simple so let me ask it  
 12 again.

13 Do you believe or -- let me ask  
 14 it this way.

15 Is it your opinion that this  
 16 particular PowerPoint presentation and its  
 17 contents are an example of how doctors were  
 18 misled by pharmaceutical messaging and  
 19 marketing?

20 MR. ARBITBLIT: Objection.

21 THE WITNESS: Yes.

22 MR. ARBITBLIT: Go ahead.

23 QUESTIONS BY MR. EHSAN:

24 Q. Doctor, if you could go back --  
 25 you can put that document aside, thank you.

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1               If you can go back to  
 2     Exhibit 17. Actually, Exhibit 1.C, which is  
 3     part of your report.

4               A.     Oh, correct.

5               Q.     Going to page 2, do you see you  
 6     have a Section B titled "Risk Understated"  
 7     and below that you have point 1 which is  
 8     states "Addiction/Abuse is rare/uncommon/less  
 9     than 1 percent."

10              Do you see that?

11              A.     Yes.

12              Q.     Now, Doctor, would you agree  
 13     that the risk of addiction abuse or misuse of  
 14     an opioid varies from patient to patient?

15              MR. ARBITBLIT: Object to form.

16              THE WITNESS: I would say that  
 17     individual factors from patient to  
 18     patient have some role in the risk of  
 19     who will develop an opioid use problem  
 20     while receiving opioids for the  
 21     treatment of chronic pain, but that  
 22     far and away the bigger risk factor is  
 23     dose and duration of that opioid.

24     QUESTIONS BY MR. EHSAN:

25     Q.     And you anticipated my next

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1               question.

2               Dose and duration of which you  
 3     are going to prescribe a medication for a  
 4     patient impacts the risk for that particular  
 5     patient of developing abuse or misuse of a  
 6     medication, correct?

7               A.     I'm sorry, could you restate  
 8     the question?

9               Q.     Sure.

10              The dose and duration for which  
 11     the prescription is written also impacts the  
 12     risk of abuse or addiction for the patient  
 13     receiving that prescription, correct?

14              A.     Yes.

15              Q.     Obviously the dose and duration  
 16     for which you're prescribing the opioid will  
 17     vary from patient to patient, correct?

18              MR. ARBITBLIT: Object to form.

19              THE WITNESS: It will vary from  
 20     patient to patient, but the general  
 21     trend over the last three decades is  
 22     high doses for long duration putting  
 23     very large cohorts of patients at high  
 24     risk.

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1     QUESTIONS BY MR. EHSAN:

2     Q.     So let me ask the question  
 3     slightly differently, Doctor.

4               If a patient was to ask you  
 5     without any additional further information,  
 6     Dr. Lembke, "What is my risk of getting  
 7     addicted to an opioid," could you answer that  
 8     question without knowing something about the  
 9     patient's background, history as well as why  
 10    the prescription is being written, for how  
 11    long and at what dose?

12              MR. ARBITBLIT: Objection.

13              Compound. Incomplete hypothetical.

14              THE WITNESS: Yes, I believe I  
 15     could answer that question.

16     QUESTIONS BY MR. EHSAN:

17     Q.     And what would you answer  
 18     that -- how would you answer that patient's  
 19     question?

20     A.     I would say to the patient that  
 21     based on the most reliable evidence, the risk  
 22     of becoming addicted to an opioid, even when  
 23     prescribed for real pain in the course of  
 24     medical treatment, is at the very least 1 in  
 25     10. So it's a very common risk and it may

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1     even be much higher than that. Volz, et al.,  
 2     which I cite in my report, talks about risk  
 3     being 8 to 12 percent for moderate to severe  
 4     opioid use disorder, and as high as  
 5     25 percent by my reading of the Volz data.  
 6     So about a quarter of patients are at risk  
 7     for developing an opioid use disorder in the  
 8     course of chronic pain treatment, which is  
 9     undoubtedly a very high risk.

10              Q.     Doctor, do you understand that  
 11     individual risk of a side effect with a  
 12     medication are a zero-one phenomenon?

13              MR. ARBITBLIT: Object to form.

14              THE WITNESS: I don't  
 15     understand your question.

16     QUESTIONS BY MR. EHSAN:

17     Q.     Sure.

18              The patient will either develop  
 19     the side effect or won't develop the side  
 20     effect, correct?

21              MR. ARBITBLIT: Object to form.

22              THE WITNESS: That's not been  
 23     my medical experience that it's cut  
 24     and dried like that.

25              Some patients will need more or

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1 less exposure to develop a side  
 2 effect. Some patients will have a  
 3 side effect if they combine that  
 4 medication with another medication.  
 5 Some patients may develop a side  
 6 effect if they develop a medical  
 7 condition that then results in that  
 8 medication leading to a side effect.

9 So it's not a --

10 QUESTIONS BY MR. EHSAN:

11 Q. So let me show you this  
 12 question.  
 13 When I would consent a patient  
 14 for surgery and if the patient asked me,  
 15 "What's my chances of dying," even assuming  
 16 that the chance of dying with a carotid  
 17 endarterectomy is 3 percent for the  
 18 institution, no one is going to die  
 19 3 percent, Doctor. They're either going to  
 20 survive the surgery or they're not going to  
 21 survive the surgery. That means 3 out of 100  
 22 may die. That's where the 3 percent comes  
 23 from, but for an individual, you either will  
 24 experience the side effect or you will not  
 25 experience the side effect.

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1 Would you agree with me on  
 2 that?

3 MR. ARBITBLIT: Object to form.  
 4 THE WITNESS: To me the salient  
 5 point is that patients actually be  
 6 given informed consent before  
 7 consenting to an intervention, whether  
 8 it's surgery or prescribing opioids.

9 QUESTIONS BY MR. EHSAN:

10 Q. I understand, Doctor.  
 11 But have you ever met a patient  
 12 who was 20 percent addicted to opioids?

13 MR. ARBITBLIT: Object to form.  
 14 THE WITNESS: I don't even  
 15 really understand your question.

16 QUESTIONS BY MR. EHSAN:

17 Q. Well, your patients are either  
 18 addicted, they carry a diagnosis of opioid  
 19 use disorder, or they don't, correct?

20 MR. ARBITBLIT: Object to form.  
 21 THE WITNESS: That's incorrect.  
 22 The DSM-V stipulates that  
 23 opioid use disorder is, in fact, a  
 24 spectrum disorder based on mild,  
 25 moderate to severe symptoms. So

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1 people can have varying degrees of  
 2 severity of their addiction.

3 QUESTIONS BY MR. EHSAN:

4 Q. But they either have an opioid  
 5 use disorder, mild, moderate or severe, or  
 6 they don't have a diagnosis of opioid use  
 7 disorder, would you agree with that?

8 A. I would not actually agree with  
 9 that, because the diagnosis of opioid use  
 10 disorder has become increasingly complex due  
 11 to changes in the criteria from DSM-IV to  
 12 DSM-V, and also given the last three decades  
 13 of the problem of overprescribing opioids for  
 14 chronic pain, there are many individuals who  
 15 are addicted to opioids who have only ever  
 16 taken them as prescribed disqualifying them  
 17 from DSM-V criteria.

18 So it is a very complicated  
 19 issue. It's not, you know, cut and dry.

20 Q. So do you have patients who you  
 21 have simultaneously diagnosed as having  
 22 opioid use disorder and not having opioid use  
 23 disorder?

24 MR. ARBITBLIT: Objection.

25 Argumentative. Misstates the

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1 testimony.

2 THE WITNESS: I don't think  
 3 that's what I said.

4 QUESTIONS BY MR. EHSAN:

5 Q. Okay. Doctor, how about before  
 6 the DSM-V criteria for opioid use disorder,  
 7 going to DSM-IV-TR where there was dependence  
 8 and abuse, do you have patients who are  
 9 simultaneously dependent and not dependent to  
 10 opioids?

11 A. The way that the DSM-IV  
 12 criteria were defined was slightly different  
 13 from the way that they actually were used in  
 14 real practice. Opioid abuse was primarily  
 15 for individuals who developed consequences  
 16 due to their opioid use, whether or not they  
 17 were physiologically dependent, and you can  
 18 be addicted without necessarily being  
 19 dependent.

20 Opioid dependence was to  
 21 characterize individuals who had had these  
 22 physiologic changes as a result of regular  
 23 use of the substance, in addition to other  
 24 psychological factors.

25 So there was this dichotomized

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1 definition. The way that it was commonly  
 2 used in practice is that for milder cases of  
 3 opioid use disorder, opioid addiction, people  
 4 would often use the opioid abuse  
 5 nomenclature. For more severe forms, they  
 6 would use the opioid dependence nomenclature.

7 With the DSM-V, they encoded  
 8 widespread recognition that opioid use  
 9 disorder is a spectrum, not everybody is  
 10 equally addicted, and some people have milder  
 11 forms and some people have more significant  
 12 forms, and based on the number of criteria  
 13 they meet, we diagnose either a mild,  
 14 moderate or severe opioid use disorder.

15 But I would say one of the most  
 16 challenging aspects in real clinical time is  
 17 the difference between people who meet DSM-V  
 18 criteria for mild opioid use disorder and  
 19 those who don't because of the new criteria  
 20 and meet criterion instead for opioid  
 21 dependence, and that can be a real hard  
 22 judgment call.

23 MR. EHSAN: Thank you, Doctor.  
 24 I move to strike as nonresponsive.  
 25 Doctor, I didn't ask you about DSM-V,

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1 but I appreciate that. But in the  
 2 interest of time, I'm going to move  
 3 on. Can I get this marked next?  
 4 (Lembke Exhibit 20 marked for  
 5 identification.)

6 QUESTIONS BY MR. EHSAN:

7 Q. Doctor, I've handed you what's  
 8 been marked as Exhibit 20. It is a package  
 9 insert from Duragesic fentanyl transdermal  
 10 system, and if you look at the very last  
 11 page, it bears an electronic signature of Bob  
 12 Rappaport, who I'll represent is from the FDA  
 13 of 2/4/2005, which is the date that this  
 14 label became effective.

15 You can see that at the very,  
 16 very last page --

17 A. Oh, here, I see.

18 Q. -- there's an electronic  
 19 signature.

20 Have you ever seen a package  
 21 insert from Duragesic before?

22 A. Yes.

23 Q. If you go to the very front  
 24 page of the document, are you aware of what a  
 25 black box is?

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1 A. Yes.  
 2 Q. What is your understanding of a  
 3 black box?  
 4 MR. ARBITBLIT: Counsel, she's  
 5 already answered that question with an  
 6 earlier inquirer. I don't want to  
 7 stop you, but --

8 MR. EHSAN: Okay.

9 MR. ARBITBLIT: -- if it's only  
 10 going to be a minute, but we're not  
 11 supposed to duplicate --

12 MR. EHSAN: That's okay.

13 MR. ARBITBLIT: -- during this  
 14 part of the process.

15 QUESTIONS BY MR. EHSAN:

16 Q. I'll move on only to say,  
 17 Doctor, could you read the first paragraph in  
 18 the black box warning of Duragesic?

19 A. "Duragesic contains a high  
 20 concentration of a potent Schedule II opioid  
 21 agonist fentanyl. Schedule II opioid  
 22 substances which include fentanyl,  
 23 hydromorphone, methadone, morphine,  
 24 oxycodone, and oxymorphone have the highest  
 25 potential for abuse and associated risk of

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1 fatal overdose due to respiratory depression.  
 2 Fentanyl can be abused and is subject to  
 3 criminal diversion. The high content of  
 4 fentanyl in the patches, Duragesic may be a  
 5 particular target for abuse and diversion."

6 Q. Doctor, do you find that  
 7 language to be false or misleading?

8 A. No.

9 Q. Do you think that a doctor  
 10 reading that portion of the package insert  
 11 for Duragesic in 2005 would adequately  
 12 understand the risks of prescribing a  
 13 fentanyl patch for a patient --

14 MR. ARBITBLIT: Object to form.

15 QUESTIONS BY MR. EHSAN:

16 Q. -- at least as it relates to  
 17 abuse or criminal diversion?

18 MR. ARBITBLIT: Object to form.

19 THE WITNESS: I think that a  
 20 prescriber reading this may take away  
 21 from it that these -- that Duragesic  
 22 and other opioids have addictive  
 23 potential, but would still not  
 24 appreciate the extent to which a  
 25 patient being treated with opioids for

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1 pain could actually get addicted in  
 2 the course of medical care because of  
 3 the misleading messaging to  
 4 prescribers communicated to them, as  
 5 long as they were prescribing opioids  
 6 for a medical condition, there was a  
 7 very rare, uncommon or less than  
 8 1 percent risk of getting addicted to  
 9 the opioid.

10 QUESTIONS BY MR. EHSAN:

11 Q. So is it your opinion, Doctor,  
 12 that despite the language saying that these  
 13 medications have the highest potential for  
 14 abuse and associated risk of fatal overdoses  
 15 due to respiratory depression, that a  
 16 physician would nevertheless accept what a  
 17 pharmaceutical representative may tell him or  
 18 her about the risk of the medication?

19 MR. ARBITBLIT: Object to form.

20 THE WITNESS: The defendants  
 21 were remarkably successful at  
 22 convincing several generations of  
 23 prescribers that the risk was so low,  
 24 as long as they were prescribing for a  
 25 medical condition, that independent of

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1 this black box warning, they need not  
 2 be concerned about that in their  
 3 patients.

4 QUESTIONS BY MR. EHSAN:

5 Q. And you agree that the black  
 6 box doesn't have anything about that this  
 7 risk is only applicable if the patient is not  
 8 taking it as prescribed, correct?

9 MR. ARBITBLIT: Object to form.

10 THE WITNESS: I didn't quite  
 11 understand your question.

12 QUESTIONS BY MR. EHSAN:

13 Q. Sure.

14 The black box language you read  
 15 didn't have any caveats about taking it as  
 16 prescribed or not as prescribed, correct?

17 A. The black box warning doesn't  
 18 address that particular issue.

19 Q. If you go back to Exhibit 17,  
 20 which is your report, Doctor?

21 A. Uh-huh.

22 Q. You can put that aside.

23 Again, on page 2, you cite  
 24 several documents that specify -- or at least  
 25 go to the topic of the understated risk in

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1 Janssen's materials.  
 2 Do you see those?  
 3 A. Yes.  
 4 Q. And several of those date back  
 5 to 2001, which are the first two bullet  
 6 points, for example, correct?  
 7 A. Yes.  
 8 Q. Now, would you agree with me  
 9 that the science in 2001 was different than  
 10 the science in 2019, as it relates to the  
 11 risk of opioid medication?

12 MR. ARBITBLIT: Object to form.

13 THE WITNESS: Not at all.

14 QUESTIONS BY MR. EHSAN:

15 Q. So it was known within the  
 16 scientific community that these medications  
 17 had the -- had a risk of addiction and abuse  
 18 that was the same in 2001 as it is today?

19 A. Well, that's a different  
 20 question, whether or not it was broadly known  
 21 what the science showed. It was certainly  
 22 known that opioids are highly addictive  
 23 dating back to the Civil War, but because --  
 24 I'm sorry, did you want to --

25 Q. No, go ahead.

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1 A. Because of the  
 2 misrepresentation of the evidence beginning  
 3 in the early 1990s, doctors were miseducated  
 4 on this point, but the evidence was not new.

5 Q. Well, when you go -- please go  
 6 to page 3 of that same section -- in your  
 7 report which is the end of that same section.  
 8 You cite -- you have a comment section. You  
 9 cite several studies, but all those  
 10 studies are from -- all those studies are  
 11 from 2008, 2004, 2004.

12 Do you see those?

13 A. So the 2008 is a Fishbain  
 14 meta-analysis, which reviews studies of the  
 15 risk of opioid addiction in the 1990s.

16 Furthermore, there were -- there were other  
 17 studies that Fishbain also reviewed in  
 18 earlier 1992 meta-analysis showing that the  
 19 risks of addiction were as much as  
 20 24 percent.

21 So it was well-known in terms  
 22 of what the actual evidence showed.

23 Q. But you don't cite any -- you  
 24 don't cite any publication that predates 2004  
 25 in your comment section; is that correct?

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1 MR. ARBITBLIT: Object to form.  
 2 THE WITNESS: The comment  
 3 section here is an augmentation of the  
 4 actual report because I decided that  
 5 to put all of these promotional  
 6 statements in the body of the report  
 7 would make it harder to read, but  
 8 they're all a piece. And I do discuss  
 9 in my report the many examples in the  
 10 literature showing higher risks of  
 11 addiction, well above the less than  
 12 1 percent, called rare, predating  
 13 2001, in fact, going back to the early  
 14 1990s.

15 QUESTIONS BY MR. EHSAN:

16 Q. Doctor, do you believe that the  
 17 use of opioids in cancer pain management is  
 18 appropriate?

19 MR. ARBITBLIT: Object to form.

20 THE WITNESS: What do you mean  
 21 by "appropriate"?

22 QUESTIONS BY MR. EHSAN:

23 Q. Do you believe that opioids can  
 24 be used effectively in the treatment of  
 25 cancer pain?

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1 MR. ARBITBLIT: Object to form.  
 2 Incomplete hypothetical.  
 3 THE WITNESS: It really would  
 4 depend on how long they were used, for  
 5 what purpose, the other circumstances  
 6 involved.

7 QUESTIONS BY MR. EHSAN:

8 Q. Do you believe opioids are  
 9 effective for the treatment of cancer pain?

10 MR. ARBITBLIT: Object to form.  
 11 THE WITNESS: I don't believe  
 12 that there's reliable evidence to show  
 13 efficacy of opioids for chronic pain,  
 14 even including pain related to cancer  
 15 pain.

16 QUESTIONS BY MR. EHSAN:

17 Q. Thank you, Doctor.

18 One last document.

19 (Lembke Exhibit 21 marked for  
 20 identification.)

21 QUESTIONS BY MR. EHSAN:

22 Q. I'm going to hand you what's  
 23 been marked as Exhibit -- sorry, I'm going to  
 24 hand you what's been marked as Exhibit 21.

25 Doctor, this is -- I apologize.

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1 This is -- the first page is just the  
 2 providence of this particular document, but I  
 3 will represent to you that -- that this is a  
 4 screen capture from a Food and Drug  
 5 Administration website, and if you can read  
 6 the tiny, tiny print on the second page of  
 7 the document itself, it says, "Page last  
 8 updated in December of 2008." It is in very  
 9 tiny print.

10 A. Yes, I can see that.

11 Q. And if you look at this  
 12 particular document, this is really tiny --  
 13 I'm trying to -- one second. I apologize.

14 Under the heading "Misuse and  
 15 Abuse," which is on the second page, the  
 16 second paragraph, and again, I apologize for  
 17 the tiny print, it states, "According to the  
 18 National Institutes of Health, studies have  
 19 shown that properly managed medical use of  
 20 opioid analgesic compounds taken exactly as  
 21 prescribed is safe, can manage pain  
 22 effectively and rarely causes addiction."

23 Do you see that, Doctor?

24 A. I don't.

25 Q. Okay.

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1 A. Oh, yes, I do, under "Misuse  
 2 and Abuse."

3 Q. Yes.

4 A. Yeah.

5 Q. Now, do you agree with that  
 6 statement from the FDA?

7 MR. ARBITBLIT: Which page are  
 8 you looking at?

9 MR. EHSAN: The second -- it's  
 10 202, under the heading "Misuse and  
 11 Abuse."

12 THE WITNESS: So --

13 MR. EHSAN: It's the second --  
 14 the second --

15 THE WITNESS: Yeah.

16 MR. EHSAN: -- I won't even call  
 17 it a paragraph, but the second full  
 18 thing.

19 THE WITNESS: So that statement  
 20 does not specify whether they're  
 21 talking about acute versus chronic  
 22 pain. In the case of acute pain, I  
 23 would agree with that statement. In  
 24 the case of chronic pain, I would  
 25 disagree with that statement.

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1 QUESTIONS BY MR. EHSAN:

2 Q. And that statement itself  
 3 doesn't clarify whether it's acute or chronic  
 4 or which one it's in reference to, correct?

5 A. That's correct.

6 MR. EHSAN: Thank you for your  
 7 time, Doctor.

8 THE WITNESS: You're very  
 9 welcome.

10 MR. ARBITBLIT: Counsel, before  
 11 we switch, I just want to point out  
 12 one thing with the document that you  
 13 introduced, which is Exhibit 19, I'm  
 14 sure it wasn't intentional, but we  
 15 have a version of that that has  
 16 meta-data attached to it that was  
 17 provided to the witness, and it did  
 18 not appear on the version that you  
 19 introduced as Exhibit 19, specifically  
 20 the -- these notes that accompanied  
 21 the PowerPoint, and we can provide a  
 22 copy to you after the deposition.

23 You can choose to replace it or  
 24 not, but the question doesn't match  
 25 the exhibit unless you have those

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1 notes with it.

2 MR. EHSAN: Oh, that's  
 3 perfectly fine. My questions were not  
 4 at all about the contents of the  
 5 document, per se. It was about the  
 6 draft language and the stamp. So if  
 7 you want to swap it out with one that  
 8 includes the speakers' notes, that's  
 9 perfectly fine.

10 MR. ARBITBLIT: Fine. Thank  
 11 you.

12 VIDEOGRAPHER: Okay. We're now  
 13 going off the record, and the time is  
 14 3:33 p.m.

15 (Off the record at 3:33 p.m.)

16 VIDEOGRAPHER: We are now going  
 17 back on the record, and the time is  
 18 3:35 p.m.

19 CROSS-EXAMINATION

20 QUESTIONS BY MR. TAM:

21 Q. Good afternoon, Doctor. My  
 22 name is Jonathan Tam, and I represent Purdue.  
 23 Have you ever been detailed by  
 24 a Purdue sales representative about  
 25 OxyContin?

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1 A. I don't recall specifically  
 2 being detailed by Purdue about OxyContin, but  
 3 I have been detailed by representatives in  
 4 the past.

5 Q. Representatives of Purdue?

6 A. Representatives of  
 7 pharmaceutical companies over the years.

8 Q. Have you been prescribed  
 9 OxyContin?

10 A. Dating all the way back to the  
 11 beginning of my medical career, I'm sure that  
 12 I have, but I don't recall any specific  
 13 situation where I prescribed it.

14 Q. So as you sit here today, you  
 15 don't recall -- strike that. Let me ask that  
 16 again.

17 Did you ever prescribe  
 18 OxyContin because of anything that a Purdue  
 19 sales representative said to you?

20 A. I don't recall a specific  
 21 event, but the messaging from Purdue pervaded  
 22 the entirety of my medical training and had a  
 23 huge impact on the way that I and my  
 24 colleagues prescribed throughout the '90s and  
 25 early aughts, including the influence, the

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1 enormous influence, on the Joint Commission  
 2 and pain as a quality measure leading to all  
 3 of us prescribing more opioids, including  
 4 OxyContin.

5 Q. So your testimony is that you  
 6 believe you have prescribed OxyContin because  
 7 of Purdue's marketing?

8 MR. ARBITBLIT: Object to form.  
 9 Misstates.

10 THE WITNESS: I believe that  
 11 due to the misrepresentations of the  
 12 benefits and risks of OxyContin, that  
 13 I have prescribed OxyContin  
 14 inappropriately at some point in my  
 15 career due to that messaging, yes.

16 QUESTIONS BY MR. TAM:

17 Q. Do you know how many OxyContin  
 18 prescriptions you wrote that you think were  
 19 inappropriate?

20 A. I don't have a specific  
 21 recollection of specific prescriptions. I'm  
 22 referring to the broader trend in OxyContin  
 23 prescribing, which is well-documented.

24 Q. Do you know whether any of  
 25 those patients that you prescribed OxyContin

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1 to became addicted to OxyContin?  
 2 A. I don't know of any patients to  
 3 whom I prescribed OxyContin who became  
 4 addicted, but I have treated many patients  
 5 who have become addicted to OxyContin through  
 6 the prescriptions of other health care  
 7 providers.

8 Q. How many patients have you  
 9 treated who were addicted to OxyContin?

10 A. It's hard for me to quantify  
 11 that. I've been practicing medicine for more  
 12 than 20 years. I see somewhere between 20  
 13 and 40 patients a week. About, I would say,  
 14 three-quarters of those patients are addicted  
 15 to opioids. That's based on my sense of it.  
 16 I haven't gone back and specifically counted,  
 17 and a large number have reported getting  
 18 OxyContin, and I currently have patients who  
 19 are addicted to OxyContin and struggling with  
 20 that in my current practice.

21 Q. You said that around 75 percent  
 22 of your patients are addicted to opioids  
 23 generally.

24 Has that figure changed over  
 25 time in the span of your career? Is it more?

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1 Is it less?  
 2 A. It has changed over time. So  
 3 in the early 1990s when I was first starting  
 4 my career, I actually didn't know much about  
 5 addiction. I didn't know how to screen or  
 6 intervene for that problem, but I became  
 7 aware of more and more of my patients who  
 8 were presenting for treatment of their  
 9 psychiatric disorders manifesting signs and  
 10 symptoms of opioid addiction, many of whom --  
 11 most of whom got those opioids from a  
 12 well-intended prescriber.

13 So I became curious about the  
 14 problem in an effort to help my patients. I  
 15 started to learn more about the problem of  
 16 addiction, and eventually I became the go-to  
 17 person in my department to help patients who  
 18 had become addicted to opioids. And so a  
 19 much larger percentage of my practice today  
 20 consists of patients addicted to OxyContin  
 21 and other opioids.

22 Honestly in the early aughts,  
 23 it could have been also a large number, but I  
 24 wasn't aware because I wasn't educated and  
 25 had asked those questions, and I didn't

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1 appreciate the risk involved because of the  
 2 way that I was trained in large part due to  
 3 the misrepresentation of the evidence.

4 Q. The patients you've treated who  
 5 were addicted to OxyContin, did any of them  
 6 die from an overdose of OxyContin?

7 A. I have had patients die of  
 8 overdoses, and I believe that there was  
 9 OxyContin involved, but I can't say for sure.

10 Q. So you can't say for sure that  
 11 the overdose was from OxyContin, can you?

12 A. That's right.

13 Q. In the patients you treat who  
 14 are addicted to OxyContin, do you know  
 15 whether they were lawfully prescribed  
 16 OxyContin by their doctors?

17 A. The vast majority of the  
 18 patients that I treat who are addicted to  
 19 opioids started out with a lawfully  
 20 prescribed opioid prescribed by their doctor  
 21 for pain.

22 Q. And is your answer the same  
 23 with respect to OxyContin specifically, so  
 24 for the patients who are addicted to  
 25 OxyContin, is it the case that most of those

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1 patients were prescribed OxyContin lawfully  
 2 from their own doctor?

3 A. Yes.

4 Q. But some of your patients did  
 5 receive OxyContin from some other source; is  
 6 that correct?

7 A. Yes.

8 Q. And what are those other  
 9 sources?

10 A. Other sources could include an  
 11 illegal online source or a dealer or an  
 12 acquaintance or a family member.

13 Q. Now, for the patients who were  
 14 prescribed OxyContin lawfully by their  
 15 doctors, do you know whether they took the  
 16 OxyContin as directed by their doctors?

17 A. The majority of my patients who  
 18 are addicted to opioids began with a lawful  
 19 prescription and took the prescription  
 20 opioid, including OxyContin, just as  
 21 prescribed.

22 Q. But did some of those patients  
 23 eventually take them in a way that was  
 24 inconsistent with their doctor's directions?

25 MR. ARBITBLIT: Object to form.

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1                   THE WITNESS: So the natural  
 2                   progression of the disease of  
 3                   addiction is that patients will need  
 4                   more and more to get the same effect.  
 5                   Often that need was actually  
 6                   accommodated by the prescriber because  
 7                   we were taught that no dose is too  
 8                   high.

9                   So I have seen patients who  
 10                  have developed addiction to OxyContin  
 11                  and other opioids manufactured by the  
 12                  defendants who only ever took their  
 13                  opioids as prescribed.

14                  And I have seen patients who  
 15                  have started out taking their opioids  
 16                  as prescribed and ultimately began to  
 17                  misuse those opioids.

18                  So I have seen the full range.

19                  QUESTIONS BY MR. TAM:

20                  Q.        And for the patients who you've  
 21                  treated that were addicted to OxyContin, were  
 22                  they also addicted to other substances?

23                  MR. ARBITBLIT: Object to form.

24                  THE WITNESS: Very frequently  
 25                  these were individuals who had no

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1                   prior history of addiction, who were  
 2                   not addicted to other substances.

3                  QUESTIONS BY MR. TAM:

4                  Q.        But there were still some  
 5                  patients that you treated who were addicted  
 6                  to OxyContin who were also addicted to other  
 7                  substances?

8                  A.        There were some patients.

9                  Q.        Can you quantify that or offer  
 10                 a percentage of your patient population for  
 11                 that?

12                 A.        I would say more of my -- of my  
 13                 patients addicted to opioids -- I would say  
 14                 approximately 80 percent of them took the  
 15                 opioid as lawfully prescribed for most of  
 16                 their opioid exposure.

17                 Q.        I appreciate that. My question  
 18                 was a little bit different.

19                 Of the patients you've treated  
 20                 who were addicted to OxyContin, what  
 21                 percentage of those were also addicted to  
 22                 other substances?

23                 A.        I can't tell you the percentage  
 24                 specifically addicted to OxyContin.

25                 In my work, that's not a major

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1                  focus. What we focus on is morphine  
 2                  milligram equivalent doses and duration and  
 3                  the aspects related to their disease of  
 4                  addiction.

5                  So I can tell you that the  
 6                  majority, 80 percent of my patients, addicted  
 7                  to opioids began taking their opioids as  
 8                  lawfully prescribed for a medical condition  
 9                  and through most of their opioid exposure  
 10                 took their medications as prescribed for that  
 11                 medical condition. So there was not deviant  
 12                 or abhorrent behavior in the majority of my  
 13                 patients, except in some portion of them at  
 14                 the very end.

15                 Q.        Have you been able to treat  
 16                 your patients who were addicted to OxyContin?

17                 A.        Yes.

18                 Q.        And have you been able to treat  
 19                 them successfully?

20                 A.        Yes.

21                 Q.        Have you conducted any research  
 22                 or analysis to determine how many  
 23                 prescriptions for Purdue opioids were written  
 24                 in Cuyahoga or Summit County for higher doses  
 25                 because of Purdue's marketing?

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1                  MR. ARBITBLIT: Object to form.  
 2                  THE WITNESS: I have analyzed  
 3                  and followed the CDC data, looking at  
 4                  the number of prescriptions in  
 5                  Cuyahoga and Summit Counties written  
 6                  per 100 persons, which does not break  
 7                  down by specific opioid.

8                  QUESTIONS BY MR. TAM:

9                  Q.        Are you done?

10                 A.        (Witness nods head.)

11                 Q.        Okay. So respectfully, I don't  
 12                 think that answers my question.

13                 Have you conducted any research  
 14                 or analysis to determine how many  
 15                 prescriptions for Purdue opioids were written  
 16                 in Cuyahoga or Summit County for higher doses  
 17                 because of Purdue's marketing?

18                 MR. ARBITBLIT: Object to form.

19                 THE WITNESS: Purdue's  
 20                 marketing was instrumental in the  
 21                 paradigm shift that I've described  
 22                 that led to minimizing the risks and  
 23                 misrepresenting the benefits that was  
 24                 at the heart of the change in pain  
 25                 management in this country.

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1           So I would say that Purdue's  
2         marketing strategies had a huge impact  
3         on Summit and Cuyahoga Counties.  
4     QUESTIONS BY MR. TAM:

5         Q.     I appreciate that's your  
6         opinion, but please focus on my question.

7           Let me try it another way. Can  
8         you tell me or quantify the number of  
9         prescriptions for Purdue opioid medications  
10        that were written in Cuyahoga or Summit  
11        Counties for higher doses because of Purdue's  
12        marketing?

13        MR. ARBITBLIT: Objection.

14        Argumentative. Asked and answered.

15        THE WITNESS: So the  
16        quadrupling of opioid prescribing that  
17        we've seen nationwide since the 1990s,  
18        including in Cuyahoga and Summit  
19        Counties and including OxyContin, is a  
20        direct result of the marketing of  
21        Purdue Pharma.

22     QUESTIONS BY MR. TAM:

23        Q.     The quadrupling of opioid  
24        prescribing, but that's all opioids, correct?

25        A.     Yes.

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1         Q.     And you attribute all of those  
2         opioid prescriptions to Purdue?  
3         MR. ARBITBLIT: Object to form.  
4         THE WITNESS: Purdue had a  
5         major role in changing the paradigm  
6         around pain treatment.

7     QUESTIONS BY MR. TAM:

8         Q.     What's your methodology for  
9         determining that they played a, quote, "major  
10        role"?

11        A.     My methodology is my personal  
12        experience having been the recipient of  
13        Purdue's marketing. My methodology is the  
14        research that I did for my book, the more  
15        than 400 articles that I've read here, my  
16        study of the way that Purdue Pharma  
17        deliberately manipulated the Joint  
18        Commission, the Federation of State Medical  
19        Boards, the Wisconsin Pain & Policy Group, in  
20        order to change opioid prescribing practices  
21        in this country.

22        Q.     Now, you referenced a  
23        quadrupling of prescriptions.

24         Is it your testimony that all  
25        of those prescriptions were for higher doses?

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1         MR. ARBITBLIT: Object to form.  
2         THE WITNESS: How would you  
3         define higher doses? How are you  
4         defining them?

5     QUESTIONS BY MR. TAM:

6         Q.     Well, your report refers to  
7         prescriptions being written in high doses,  
8         correct?

9         MR. ARBITBLIT: Object to form.  
10        THE WITNESS: My report cites  
11        evidence showing that dose and  
12        duration directly impact the risk of  
13        overdose and opioid use disorder.

14     QUESTIONS BY MR. TAM:

15        Q.     What would you consider a high  
16        dose of OxyContin?

17        A.     I base it on morphine milligram  
18        equivalents consistent with the CDC  
19        guidelines, anything over 90 morphine  
20        milligram equivalents, but in my report I  
21        also qualify that patients can suffer  
22        morbidity and mortality even at lower doses.

23        Q.     So in the quadrupling statistic  
24        that you gave to me, you can't differentiate  
25        which of those prescriptions were for high or

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1         low doses, can you?  
2         MR. ARBITBLIT: Object to form.  
3         THE WITNESS: The point that I  
4         made with the quadrupling -- well,  
5         actually, let me look at my report.  
6         So in my report I cite  
7         Paulozzi --

8     QUESTIONS BY MR. TAM:

9         Q.     What page are you on?  
10        A.     I'm sorry, I'm on page 11.

11         "By 2005 long-term opioid  
12        therapy was being prescribed to an estimated  
13        10 million US adults. The volume of  
14        prescribed opioid analgesics was 100 morphine  
15        milligram equivalents per person in 1997.

16         "In 2007, the morphine  
17        milligram equivalent per person had increased  
18        to almost 700 morphine milligram equivalents.

19         "And a very recent study found  
20        that the 2017 level of morphine milligram  
21        equivalents had declined from its peak to 543  
22        morphine milligram equivalents, which remain  
23        well over five times higher than the  
24        prescribing rate in 1997."

25         So my answer is due to Purdue's

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1 marketing and that of the other defendants,  
 2 there was not just an increase in the number  
 3 of prescriptions, but also a large increase  
 4 in the number of prescriptions written for  
 5 chronic therapy and the dose written to  
 6 patients.

7 Q. But you can't give me a  
 8 specific number of prescriptions of OxyContin  
 9 in Cuyahoga or Summit County, can you?

10 MR. ARBITBLIT: Object to form.

11 THE WITNESS: I don't really  
 12 think it's relevant, but I can't give  
 13 you a specific number.

14 QUESTIONS BY MR. TAM:

15 Q. If you could turn to -- I think  
 16 it's Exhibit 17, which is Appendix I.A -- I.A  
 17 of your report, sorry. And I.A is the part  
 18 about Purdue.

19 Are you with me, Doctor?

20 A. Yes. Appendix I.A, page 1.

21 Q. Yes.

22 So can we agree that all of the  
 23 documents that you cite in here that you  
 24 attribute to Purdue are all dated 2001 or  
 25 earlier?

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1 A. No. The first one is 1997.

2 Q. Let me just make sure you  
 3 understand my question.

4 I said -- I asked, can we agree  
 5 that all of the documents that you cite in  
 6 here that you attribute to Purdue are all  
 7 dated from 2001 or earlier, from before 2001?

8 A. Oh, let me take a look.

9 MR. ARBITBLIT: While she's  
 10 looking at it, I just wanted to point  
 11 out that Exhibit 17 did not include  
 12 the complete appendices and we  
 13 included Janssen, so your reference to  
 14 Exhibit 17, I don't think that  
 15 document the witness has been asked to  
 16 review now has been marked as an  
 17 exhibit.

18 MR. TAM: Thank you for that  
 19 clarification.

20 Do you have a copy?

21 MR. ARBITBLIT: Other than it  
 22 might be part of the Exhibit 1, the  
 23 report, it's not --

24 THE WITNESS: Yes, we can agree  
 25 they are all dated 2001 or earlier.

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1 QUESTIONS BY MR. TAM:

2 Q. Thank you.

3 And to address counsel's  
 4 clarification, I appreciate it, I did refer  
 5 to Exhibit 17, which is just the Janssen  
 6 portion of Appendix I, but for the record,  
 7 Exhibit 13 is the entire Exhibit 1, which  
 8 would include the section that has the Purdue  
 9 statements.

10 MR. ARBITBLIT: Okay.

11 QUESTIONS BY MR. TAM:

12 Q. Did you review any documents  
 13 that Purdue produced from 2002 or later?

14 A. I reviewed a lot of documents,  
 15 and I didn't focus on the dates, so I'm not  
 16 sure.

17 Q. Can you identify a doctor from  
 18 Summit or Cuyahoga County who saw any of the  
 19 documents that you cite in Appendix I.A?

20 MR. ARBITBLIT: Object to form.

21 THE WITNESS: I would answer  
 22 what I answered to a similar question  
 23 that was asked prior, that the kind of  
 24 misrepresentation that I describe in  
 25 my report was widespread and Cuyahoga

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1 and Summit Counties would not have  
 2 been exempt from that. So I believe  
 3 that the doctors in Cuyahoga and  
 4 Summit Counties were exposed to this  
 5 misrepresented evidence as a result of  
 6 the defendants' marketing.

7 QUESTIONS BY MR. TAM:

8 Q. And I appreciate that's your  
 9 opinion. I'm just trying to understand the  
 10 bounds of it.

11 So you're not going to come  
 12 into court at trial and identify any Summit  
 13 County or Cuyahoga County doctor who you say  
 14 saw any of these documents in Appendix I.A,  
 15 are you?

16 A. Not unless you ask me to review  
 17 some specific document.

18 Q. And as you sit here today,  
 19 you're not aware of any specific Cuyahoga or  
 20 Summit County doctor who saw any of the  
 21 documents that you cite in Appendix A?

22 MR. ARBITBLIT: Object to form.

23 QUESTIONS BY MR. TAM:

24 Q. Right?

25 MR. ARBITBLIT: Sorry.

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1                   THE WITNESS: I'm not aware of  
 2                   a specific doctor, but I believe that  
 3                   doctors more broadly in Cuyahoga and  
 4                   Summit Counties have been exposed to  
 5                   these marketing messages, as we all  
 6                   were.

7                   QUESTIONS BY MR. TAM:

8                   Q.       And you can't identify any  
 9                   doctor in Cuyahoga or Summit County who  
 10                  relied on any of the statements or the  
 11                  content in the documents cited in  
 12                  Appendix I.A when they prescribed a Purdue  
 13                  opioid medication to their patients, can you?

14                  A.      Again, I would say I can't cite  
 15                  a specific individual, but more broadly, all  
 16                  physicians in the last two-plus decades have  
 17                  been misled by these false marketing  
 18                  messages, and it has fundamentally changed  
 19                  the way that opioids have been prescribed.

20                  Q.      Now, some of the documents you  
 21                  cite in Appendix I.A are from third parties,  
 22                  not Purdue, correct?

23                  MR. ARBITBLIT: Object to form.  
 24                  THE WITNESS: Could you define  
 25                  third parties?

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1                   QUESTIONS BY MR. TAM:

2                   Q.      Sure, why don't we do it this  
 3                   way.

4                   Can you turn to page 7 of  
 5                   Appendix I.A, and you see your section  
 6                   heading number 4?

7                   A.      Yes.

8                   Q.      And then the first bullet under  
 9                   there, you cite a CME course, right?

10                  A.     Uh-huh.

11                  Q.      And you note that this CME  
 12                  course was supported by an education grant  
 13                  from Purdue Pharma and distributed by  
 14                  familypractice.com.

15                  Do you see that?

16                  A.      Yes, I do.

17                  Q.      So it's your understanding that  
 18                  Purdue provided a grant for this CME, right?

19                  A.      That's my understanding, yes.

20                  Q.      Have you seen any evidence that  
 21                  demonstrates that Purdue controlled or  
 22                  dictated the content of this specific CME  
 23                  course?

24                  A.      There is evidence that when a  
 25                  pharmaceutical company sponsors a continuing

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1                   medical education event, that the physicians  
 2                   who leave that -- after having participated  
 3                   in that CME are more likely to prescribe the  
 4                   drug produced by the pharmaceutical company  
 5                   that sponsored the CME event.

6                   Q.      My question was a little  
 7                   different.

8                   Have you seen any evidence  
 9                   about this particular CME that demonstrates  
 10                  that Purdue controlled or dictated the  
 11                  content of the CME?

12                  MR. ARBITBLIT: Object to form.

13                  THE WITNESS: I don't really  
 14                  think that that's that relevant. I  
 15                  think that the reason that Purdue  
 16                  funds continuing medical education  
 17                  courses is precisely to promote the  
 18                  false messaging because they have  
 19                  found that that's a very effective  
 20                  strategy for doing that.

21                  QUESTIONS BY MR. TAM:

22                  Q.      Doctor, I appreciate if you  
 23                  think it's irrelevant, but I'm entitled to  
 24                  ask my questions.

25                  Can you point me any evidence

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1                   that demonstrates that Purdue controlled or  
 2                   dictated the content of this CME?

3                   MR. ARBITBLIT: Object to form.  
 4                   THE WITNESS: I'll refer you to  
 5                   page 19 of my report, in which I quote  
 6                   from an article by Van Zee called "The  
 7                   Promotion and Marketing of OxyContin,  
 8                   Commercial Triumph, Public Health  
 9                   Tragedy." Quote, "From 1996 to 2001,  
 10                  Purdue conducted more than 40 national  
 11                  pain management and speaker training  
 12                  conferences at resorts in Florida,  
 13                  Arizona and California. More than  
 14                  5,000 physicians, pharmacists and  
 15                  nurses attended these all-expense paid  
 16                  symposia where they were recruited and  
 17                  trained for Purdue's national speaker  
 18                  bureau. It is well-documented that  
 19                  this type of pharmaceutical company  
 20                  symposium influences physicians'  
 21                  prescribing even though the physicians  
 22                  who attend such symposia believe that  
 23                  such enticements do not alter their  
 24                  prescribing patterns."

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1     QUESTIONS BY MR. TAM:

2       Q.     Doctor, nothing that you just  
3     read from the Van Zee study says that by  
4     funding a program Purdue has controlled or  
5     dictated the content of that program, right?

6           MR. ARBITBLIT: Object to form.

7        THE WITNESS: I would disagree,  
8     but that is the very reason that  
9     Purdue and the other defendants fund  
10    these CMEs, because the CMEs promote  
11    their messages, key opinion leaders  
12    who promote the use of their drugs are  
13    invited and sponsored as speakers at  
14    these CMEs. That's how the whole  
15    system works.

16    QUESTIONS BY MR. TAM:

17       Q.     Are you going to be offering  
18    testimony about the intent of defendants when  
19    providing funding for CMEs?

20           MR. ARBITBLIT: Object to form.

21        THE WITNESS: It's not a matter  
22    of offering an opinion on the intent.  
23    It's a matter of looking at the whole  
24    system and recognizing the patterns of  
25    influence and the way in which Purdue

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1       Pharma and other defendants covertly  
2     infiltrated physician education in  
3     order to promote their false messages.

4     QUESTIONS BY MR. TAM:

5       Q.     So your opinion is that by  
6     providing funding, a pharmaceutical  
7     company -- strike that. Let me try it again.  
8       Your opinion is that when a  
9     pharmaceutical company provides funding for a  
10    program, it is necessarily controlling and  
11    dictating the content of the program simply  
12    by virtue of providing the funding?

13           MR. ARBITBLIT: Object to form.

14        Misstates the record.

15        THE WITNESS: I think you've  
16    misstated my words.

17       What I am saying, and it's my  
18    opinion, but it's also based in  
19    evidence, that when a pharmaceutical  
20    company funds a continuing medical  
21    education course, it has a direct  
22    impact on the way that physicians  
23    prescribe, such that they are more  
24    likely to prescribe the medication  
25    that is manufactured by that company.

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1     QUESTIONS BY MR. TAM:

2       Q.     Right.

3        But my questions aren't  
4     directed about -- at what physicians are  
5     likely to do after they attend a CME.

6        My question is about the  
7     content in the CME itself.

8        Are you with me, Doctor?

9       A.     Yes.

10      Q.     So are you familiar with what  
11    unrestricted grants are?

12      A.     Yes.

13      Q.     Have you ever received an  
14    unrestricted grant?

15      A.     I have.

16      Q.     So what's an unrestricted  
17    grant?

18      A.     An unrestricted grant is a  
19    grant whereby an individual can use those  
20    funds for whatever they want, essentially.

21      Q.     And when you receive an  
22    unrestricted grant --

23      A.     By the way, let me -- just --  
24    I'm sorry.

25      Q.     No.

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1       A.     I just want to say I've not --  
2     I've never received an unrestricted grant  
3     from a pharmaceutical company. I've received  
4     unrestricted grants from Stanford for  
5     educational material that I worked on.

6       Q.     Okay. So you anticipated one  
7     of my questions.

8       But --

9       A.     Sorry to interrupt.

10      Q.     -- when you receive an  
11    unrestricted grant, that means that the  
12    sponsor, the one who provided you the money,  
13    does not control or dictate what you do with  
14    that money or how you conduct your research,  
15    right?

16           MR. ARBITBLIT: Object to form.

17        THE WITNESS: What I think your  
18    line of questioning is missing is the  
19    subtle forms of influence because of  
20    the relationship that occurs between  
21    the individual who receives the grant  
22    from the pharmaceutical company and  
23    what they then choose to emphasize in  
24    a continuing medical education course.

25       And there's good evidence in my

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1 report about the way in which Purdue  
 2 Pharma and other defendants enlisted  
 3 key opinion leaders and promoted their  
 4 careers and had them speak at  
 5 continuing medical education courses.

## 6 QUESTIONS BY MR. TAM:

7 Q. When you receive an  
 8 unrestricted grant, your work is done  
 9 independent of the sponsor or the funder,  
 10 correct?

11 MR. ARBITBLIT: Object to form.

12 THE WITNESS: There is an  
 13 important difference between receiving  
 14 unrestricted grant from the university  
 15 or from a purely educational entity  
 16 versus receiving an unrestricted grant  
 17 from a pharmaceutical company that has  
 18 a profit agenda. And there's lots of  
 19 evidence to show that when physicians  
 20 accept even small gifts from a  
 21 pharmaceutical company, even in  
 22 unrestricted form, that will affect  
 23 their prescribing. And there's lots  
 24 of evidence to show that. Wazana, et  
 25 al., is one of the -- one of the many

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1 articles showing that, and I do cite  
 2 that in the report.  
 3 MR. TAM: Respectfully I'm  
 4 going to move to strike that answer as  
 5 nonresponsive.

## 6 QUESTIONS BY MR. TAM:

7 Q. When you receive an  
 8 unrestricted grant, your work is done  
 9 independent of the sponsor or funder,  
 10 correct?

11 MR. ARBITBLIT: Object to form.

12 Misstates.

13 THE WITNESS: When I receive an  
 14 unrestricted grant, I would like to  
 15 believe that my work is done  
 16 independently, but I concede that  
 17 there may be some influence based on  
 18 the source of the funding because it's  
 19 human nature to want to please and be  
 20 in positive relationships to those  
 21 people who give us money or other  
 22 forms of, you know, financial wealth.

23 One thing that's clear is the  
 24 way in which Purdue Pharma cultivated  
 25 relationships with thought leaders in

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1 pain medicine in order to influence  
 2 prescribing, and I give many examples  
 3 in my report from the Pain & Policy  
 4 Study Group to the Joint Commission to  
 5 the changes in the DSM-V.

6 MR. TAM: I'm going to move to  
 7 strike that second paragraph in your  
 8 answer as nonresponsive.

## 9 QUESTIONS BY MR. TAM:

10 Q. Doctor, you're being paid as an  
 11 expert in this case, right?

12 A. Yes.

13 Q. Do you think you're influenced  
 14 by plaintiffs' lawyers?

15 A. My opinions in my report were  
 16 formed before I ever had contact with the  
 17 plaintiffs' lawyers. I'm on the record  
 18 publicly in my book and with my opinions in  
 19 this. So I think that although we're all  
 20 susceptible to influence, including myself, I  
 21 think that I have not been influenced by the  
 22 plaintiffs' lawyers in this case.

23 Q. What about other experts who,  
 24 unlike you, have not published their opinions  
 25 prior to becoming experts in this litigation?

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1 MR. ARBITBLIT: Object to form.  
 2 Speculative.

3 THE WITNESS: I would like to  
 4 think they're not influenced either.

## 5 QUESTIONS BY MR. TAM:

6 Q. Have you reviewed any  
 7 agreements between Purdue and the Pain &  
 8 Policy Study Group?

9 A. Yes, I have.

10 Q. And did you see documents that  
 11 made clear that the funding that Purdue was  
 12 providing was in the form of an unrestricted  
 13 grant?

14 MR. ARBITBLIT: Object to form.

15 THE WITNESS: I have reviewed  
 16 documents that have showed numerous  
 17 defendants providing funding to the  
 18 Pain & Policy Study Group over many  
 19 years, which I think had a direct  
 20 impact on the false messaging that  
 21 changed the practice of opioid  
 22 prescribing in pain treatment.

23 MR. TAM: Respectfully move to  
 24 strike as nonresponsive.

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1 QUESTIONS BY MR. TAM:

2 Q. But can we agree that those  
 3 were unrestricted grants between -- that were  
 4 provided by Purdue to the Pain & Policy  
 5 Studies Group?

6 MR. ARBITBLIT: Object to form.

7 THE WITNESS: I can't agree  
 8 with that just because I don't --  
 9 didn't see anywhere where it said  
 10 unrestricted grant. I believe you  
 11 that it may be an unrestricted grant,  
 12 but I didn't see the payments  
 13 highlighted as restricted or  
 14 unrestricted.

15 And as I've already stated, I  
 16 don't think it would make a big  
 17 difference whether or not they were  
 18 restricted or unrestricted.

19 (Lembke Exhibit 22 marked for  
 20 identification.)

21 QUESTIONS BY MR. TAM:

22 Q. Can we mark this document as  
 23 the next exhibit, please? I am handing you  
 24 what I've marked as Exhibit 22. All right.

25 Doctor, do you see that this is

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1 a letter from the Pain &amp; Policy Studies Group

2 to Purdue?

3 A. Yes.

4 Q. And it's dated October 5, 2006?

5 A. Yes.

6 Q. Okay. So the second paragraph  
 7 says, "The purpose of this letter is to  
 8 confirm that this contribution is intended as  
 9 a gift and that all parties agree to the  
 10 general conditions concerning gifts to  
 11 UW-Madison. The university defines a gift  
 12 and funding provided for general or  
 13 unrestricted support for research, public  
 14 service, instruction, fellowship,  
 15 traineeships or other activities."

16 Do you see that?

17 A. Yes, I do.

18 Q. And if you look later in the  
 19 paragraph, the second to the last sentence,  
 20 it says, "The donor may not restrict  
 21 publication by the university of the results  
 22 of the work resulting from the gift in any  
 23 way."

24 Do you see that?

25 A. Yes.

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1 Q. All right. So can we agree  
 2 that this document says that at least the  
 3 \$50,000 being provided by Purdue is  
 4 unrestricted?

5 A. Yes.

6 Q. And are you aware that Purdue  
 7 provided the Joint Commission with  
 8 unrestricted grants?

9 MR. ARBITBLIT: Object to form.  
 10 THE WITNESS: I guess I would  
 11 like to see specific material on that.  
 12 I'm aware that Purdue Pharma provided  
 13 the Joint Commission with educational  
 14 material they disseminated. I  
 15 wouldn't be at all surprised if they  
 16 also provided unrestricted grants, but  
 17 I can't say that I recall specific  
 18 unrestricted grants.

19 MR. TAM: Doctor, I think  
 20 that's my time. So I will reserve our  
 21 rights and subject to any questioning  
 22 that your counsel may have, concede my  
 23 time to -- or pass the time to the  
 24 next counsel.

25 VIDEOPHOTOGRAPHER: We are now going

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1 off the record, and the time is  
 2 4:13 p.m.

3 (Off the record at 4:13 p.m.)

4 VIDEOPHOTOGRAPHER: We're now going  
 5 back on the record, and the time is  
 6 4:16 p.m.

7 (Lembke Exhibit 23 marked for  
 8 identification.)

9 CROSS-EXAMINATION

10 QUESTIONS BY MR. STAMPFL:

11 Q. Good afternoon, Doctor. My  
 12 name is Karl Stampfl, and I represent the  
 13 Allergan defendants. I've marked your  
 14 Materials Considered list as Exhibit 23.

15 Do you have it in front of you?

16 A. Yes.

17 Q. And is this the document where  
 18 you listed the materials you considered in  
 19 forming the opinions in your report?

20 A. Yes, it is.

21 Q. Could you turn to the page 33  
 22 of Exhibit 23?

23 Do you see there that beginning  
 24 at Entry 425 you list what you call  
 25 Bates-stamped documents?

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1 A. Yes.  
 2 Q. That's where the documents that  
 3 you considered that came from the defendants'  
 4 files, among others, are listed, correct?

5 A. Yes.  
 6 Q. You listed five documents that  
 7 were produced by my client, Allergan,  
 8 correct?

9 A. Yes.  
 10 Q. Were you aware that Allergan  
 11 produced hundreds of thousands of documents  
 12 in this case?

13 A. Yes.  
 14 Q. How did you select these five  
 15 documents to review out of those hundreds of  
 16 thousands?

17 A. These documents were provided  
 18 to me by counsel.

19 Q. Do you think it's fair to opine  
 20 about Allergan's marketing conduct based on  
 21 review of only five out of hundreds of  
 22 thousands of documents?

23 MR. ARBITBLIT: Object to form.  
 24 THE WITNESS: I do think that  
 25 it's fair, yes.

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1 QUESTIONS BY MR. STAMPFL:  
 2 Q. You have no idea what were in  
 3 the other hundreds of thousands of documents,  
 4 right?  
 5 MR. ARBITBLIT: Object to form.  
 6 THE WITNESS: I think it's fair  
 7 because for 20 years, I was the  
 8 recipient as a practicing physician of  
 9 this misleading marketing, so I have a  
 10 pretty good idea of what that  
 11 constitutes.

12 And in reading the documents  
 13 that I did, I felt like the themes  
 14 were pretty well-saturated, and I  
 15 didn't feel the need to read  
 16 additional documents.

17 QUESTIONS BY MR. STAMPFL:

18 Q. Can you identify any statement  
 19 that you're aware of prior to this case from  
 20 Allergan?

21 MR. ARBITBLIT: Object to form.  
 22 THE WITNESS: I believe that  
 23 Allergan's statements are pieced with  
 24 the other defendants, that this is  
 25 overall the marketing messaging that

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1 they participated in collectively to  
 2 change the practice of opioid  
 3 prescribing by misrepresenting the  
 4 risks and benefits.

5 QUESTIONS BY MR. STAMPFL:

6 Q. But you're not basing that on  
 7 anything beyond these five documents out of  
 8 hundreds of thousands, right?

9 MR. ARBITBLIT: Object to form.  
 10 Misstates.

11 THE WITNESS: I'm basing this  
 12 on my experience as a physician, being  
 13 trained in the climate that was  
 14 affected by the defendants' actions  
 15 regarding these misleading messages,  
 16 as well as these specific documents  
 17 that I reviewed from Allergan.

18 QUESTIONS BY MR. STAMPFL:

19 Q. Have you ever been detailed by  
 20 an Allergan or Actavis sales representative  
 21 about Kadian?

22 A. Not to my specific  
 23 recollection.

24 Q. Do you know anyone who's ever  
 25 been detailed by any Allergan or Actavis

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1 sales representative about Kadian?  
 2 A. Not to my specific  
 3 recollection.

4 Q. Prior to your involvement in  
 5 this case, did you know that Allergan sold  
 6 opioids?

7 A. Yes.

8 Q. What opioids?

9 A. Kadian, which is long-acting  
 10 morphine sulfate, and then it's also my  
 11 understanding that Allergan acquired Teva  
 12 Pharmaceuticals.

13 Is that accurate?

14 Q. I can't testify, but I can  
 15 represent to you that, no, that's not --

16 A. Okay.

17 Q. -- that's not accurate.

18 A. Okay.

19 Q. So let me ask you: Sitting  
 20 here today, can you identify any other  
 21 opioids that Allergan sold?

22 A. No.

23 Q. Do you recall mentioning  
 24 Allergan or Actavis even once in your book  
 25 "Drug Dealer, MD"?

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1           A.     No, but the emphasis of my book  
 2     was not specific opioids. It was the problem  
 3     of opioid -- opioids more generally and the  
 4     misrepresentation of the evidence and the  
 5     promoting of false messages more generally.

6           Q.     Now, you said a little bit  
 7     earlier that the opinions in your report you  
 8     put out into the public in your book and in  
 9     other public statements prior to your report.

10          Do you recall that testimony?

11          MR. ARBITBLIT: Objection.

12          Object to form. Misstates.

13          THE WITNESS: Could you clarify  
 14         the question?

15          QUESTIONS BY MR. STAMPFL:

16          Q.     Yeah.

17          Didn't you just testify in  
 18     response to Purdue's counsel questioning that  
 19     we can know that you hadn't been influenced  
 20     by plaintiffs' lawyers because you had  
 21     published your opinions prior to your putting  
 22     out your report in this case.

23          Do you recall that testimony?

24          A.     I recall that testimony, but I  
 25     think it's -- if I said that, it's a

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1     misstatement.

2           I had opinions based on my own  
 3     research prior to being involved in this  
 4     litigation.

5           Since being involved in this  
 6     litigation, I've had the opportunity to  
 7     evaluate many more documents, which has only  
 8     served to augment my opinions and elaborate  
 9     on them. I haven't changed my opinions.

10         They've been strengthened by the opportunity  
 11     to review additional documents.

12          Q.     And the additional documents  
 13     that you've reviewed that were produced by my  
 14     client were five out of hundreds of  
 15     thousands; is that right?

16          MR. ARBITBLIT: Object to form.  
 17          Asked and answered. Argumentative.

18          THE WITNESS: I think I  
 19         answered that.

20          QUESTIONS BY MR. STAMPFL:

21          Q.     Is it correct?

22          MR. ARBITBLIT: Object to form.  
 23          THE WITNESS: I reviewed these  
 24     documents that are listed in the  
 25     Bates-stamped documents.

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1     QUESTIONS BY MR. STAMPFL:

2          Q.     It's certainly fair to say,  
 3     Doctor, that you didn't review many more  
 4     documents produced by Allergan, right?

5          MR. ARBITBLIT: Object to form.

6          THE WITNESS: I didn't feel it  
 7     was necessary.

8     QUESTIONS BY MR. STAMPFL:

9          Q.     You just made assumptions about  
 10    Allergan based on the fact that it was a  
 11    defendant in this case, right?

12          MR. ARBITBLIT: Object to form.

13          Argumentative. Misstates the record.

14          THE WITNESS: I don't believe I  
 15     made assumptions. I based my  
 16     assumptions on the documents that I  
 17     reviewed, on my clinical experience,  
 18     on my own research on the opioid  
 19     epidemic.

20     QUESTIONS BY MR. STAMPFL:

21          Q.     Can you point to any research  
 22     that you did about Allergan or anything it  
 23     did or said prior to your report?

24          MR. ARBITBLIT: Object to form.

25          THE WITNESS: So this appendix

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1     lists specific misrepresentations of  
 2     the evidence, which are consistent  
 3     more broadly with the  
 4     misrepresentations by other  
 5     defendants, and which are, I believe,  
 6     instrumental in leading to the opioid  
 7     epidemic.

8     QUESTIONS BY MR. STAMPFL:

9          Q.     We can agree, can't we, Doctor,  
 10    that it wouldn't be fair to blame Allergan  
 11    for anything that any other defendant did or  
 12    said, right?

13          MR. ARBITBLIT: Object to form.

14          THE WITNESS: I wouldn't  
 15     necessarily agree with that. I think  
 16     that there was a way in which the  
 17     defendants utilized the messaging in  
 18     concert to advance their own agendas.

19     QUESTIONS BY MR. STAMPFL:

20          Q.     You're aware, aren't you, that  
 21    Allergan didn't acquire Kadian until  
 22    December 2008, right?

23          A.     I was not aware of that.

24          Q.     You didn't consider that fact  
 25     in formulating the opinions in your report?

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1 A. No.  
 2 (Lembke Exhibit 24 marked for  
 3 identification.)  
 4 QUESTIONS BY MR. STAMPFL:  
 5 Q. I'm going to mark an excerpt  
 6 from plaintiffs' complaint as Exhibit 24.  
 7 And you reviewed plaintiffs'  
 8 complaint you testified earlier, right,  
 9 Dr. Lembke?  
 10 A. Yes.  
 11 Q. And could you look at  
 12 paragraph 51 from the excerpt I just marked?  
 13 A. I'm sorry, is it numbered --  
 14 Q. Paragraph 51 is on page 16.  
 15 A. Yeah.  
 16 Q. Do you see here that  
 17 plaintiffs' complaint states in the middle of  
 18 paragraph 51, "In 2008, Actavis, Inc., now  
 19 known as Allergan Finance, LLC, acquired the  
 20 opioid, Kadian, through its subsidiary,  
 21 Actavis Elizabeth, LLC, which had been the  
 22 contract manufacturer of Kadian since 2005."  
 23 Do you see that?  
 24 A. Yes, I do.  
 25 Q. So do you agree then that

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1 Allergan didn't acquire Kadian until December  
 2 of 2008?  
 3 A. Yes.  
 4 Q. So you have no basis to claim  
 5 that Allergan or Actavis caused any rise in  
 6 prescriptions prior to 2009, right?  
 7 MR. ARBITBLIT: So just to  
 8 interject, it calls for a legal  
 9 conclusion. Objection.  
 10 QUESTIONS BY MR. STAMPFL:  
 11 Q. I'm glad to repeat the question  
 12 for you.  
 13 A. Please, thanks.  
 14 Q. Do you have any reason to  
 15 believe that Allergan or Actavis caused any  
 16 rise in prescriptions in 2009 when it  
 17 acquired Kadian?  
 18 MR. ARBITBLIT: Object -- same  
 19 objection. Calls for a legal  
 20 conclusion.  
 21 THE WITNESS: No.  
 22 QUESTIONS BY MR. STAMPFL:  
 23 Q. Do you have any basis to claim  
 24 that Allergan or Actavis caused what you  
 25 referred to as the epidemic of prescription

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1 opioid use to the extent that epidemic  
 2 occurred prior to 2009?  
 3 MR. ARBITBLIT: Same objection.  
 4 Calls for a legal conclusion.  
 5 THE WITNESS: No.  
 6 QUESTIONS BY MR. STAMPFL:  
 7 Q. You have no basis to claim that  
 8 Allergan or Actavis caused the opioid crisis  
 9 to the extent it occurred prior to 2009,  
 10 correct?  
 11 MR. ARBITBLIT: Calls for a  
 12 legal conclusion.  
 13 THE WITNESS: Correct.  
 14 QUESTIONS BY MR. STAMPFL:  
 15 Q. In fact, isn't it true that by  
 16 2010, shortly after what was then known as  
 17 Actavis acquired Kadian, opioid prescriptions  
 18 had begun decreasing?  
 19 A. Opioid prescriptions began  
 20 decreasing around 2012, so there was quite a  
 21 bit of time between 2009, when Actavis  
 22 acquired Kadian, and 2012.  
 23 Q. Could you look at paragraph 14  
 24 C of your report, please?  
 25 Do you have your report in

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1 front of you, Doctor?  
 2 A. I do.  
 3 MR. ARBITBLIT: Do you have a  
 4 page number?  
 5 MR. STAMPFL: I don't. It's  
 6 paragraph 14 C. I'll try to get one  
 7 for you. I believe it's page 87.  
 8 QUESTIONS BY MR. STAMPFL:  
 9 Q. Now, I know you just said 2012,  
 10 but do you see that here in paragraph 14 C,  
 11 second sentence, you write, "Opioid  
 12 prescriptions per person in the total US  
 13 increased annually at an average rate of  
 14 6.9 percent per year until 2010 and decreased  
 15 at an average rate of 3.8 percent per year  
 16 from 2010 until -- or through 2015."  
 17 Do you see that, Doctor?  
 18 A. Uh-huh.  
 19 Q. Do you agree that by 2010,  
 20 shortly after Actavis acquired Kadian, opioid  
 21 prescriptions began, in fact, decreasing?  
 22 A. Well, this is opioid  
 23 prescriptions per person, so there are  
 24 multiple ways to measure this.  
 25 Q. Okay. In that case, I'll

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1 withdraw my question and revise it.  
 2 Do you agree that by 2010,  
 3 shortly after Actavis acquired Kadian, opioid  
 4 prescriptions per person had begun  
 5 decreasing?

6 A. Yes.

7 Q. Do you agree that by 2010,  
 8 shortly after Actavis acquired Kadian, MME  
 9 per person had begun decreasing?

10 And the reference is the next  
 11 sentence, 14 C.

12 A. Yes.

13 Q. Would the opioid crisis have  
 14 occurred had Actavis never purchased and  
 15 promoted Kadian?

16 MR. ARBITBLIT: Object to form.

17 THE WITNESS: I think the  
 18 opioid crisis would have occurred  
 19 had -- independent of that.

20 QUESTIONS BY MR. STAMPFL:

21 Q. Isn't it fair to say, Doctor,  
 22 that Allergan didn't cause the opioid crisis?

23 MR. ARBITBLIT: Object to form.

24 THE WITNESS: I believe that  
 25 all of the defendants played some

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1 role, but based on this timeline, it  
 2 does appear that Allergan's role may  
 3 be less.

4 QUESTIONS BY MR. STAMPFL:

5 Q. Don't you think to the extent  
 6 that Allergan had any role in the opioid  
 7 crisis, it was very limited?

8 MR. ARBITBLIT: Object to form.

9 THE WITNESS: I actually  
 10 believe that the opioid crisis  
 11 continues to this day, and that these  
 12 misrepresentations continue to be a  
 13 problem. And so to the extent that  
 14 Allergan is contributing to that  
 15 problem, Allergan has responsibility.

16 QUESTIONS BY MR. STAMPFL:

17 Q. I understand.

18 So when was the last time  
 19 Allergan promoted Kadian in any way?

20 And, Doctor, are you referring  
 21 now to Appendix I.E?

22 A. Yes, I am.

23 Q. And I'll represent to you that  
 24 the latest date you have in there is  
 25 February 2013.

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1 Does that sound right to you?  
 2 A. Yes, it does.  
 3 Q. Can you identify any allegedly  
 4 inappropriate Allergan statements after  
 5 February 2013?

6 A. I would have to re-review the  
 7 documents, specifically paying attention to  
 8 dates, which is not something that I paid  
 9 attention to.

10 Q. And the documents that you  
 11 would have to re-review are the five  
 12 documents that you considered about Allergan,  
 13 correct?

14 A. Yes.

15 Q. Were you aware that in  
 16 Appendix I.E you, in fact, relied on  
 17 documents that weren't marketing or even  
 18 training materials from Allergan but rather  
 19 Kadian's prior owner, Alpharma?

20 A. I wasn't aware of that because  
 21 they were Bates stamped or -- Allergan.

22 Q. You understand that the Bate  
 23 stamp just means who produces the document,  
 24 not who used or created the document, right?

25 A. Yes.

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1 Q. So do you have any basis to try  
 2 to hold Allergan responsible for anything  
 3 that the prior, unaffiliated owner of Kadian  
 4 did or said?

5 MR. ARBITBLIT: Objection.  
 6 Argumentative. And calls for a legal  
 7 conclusion.

8 THE WITNESS: Well, it doesn't  
 9 matter so much who produced the  
 10 document. It's whether or not  
 11 Allergan used the document.

12 QUESTIONS BY MR. STAMPFL:

13 Q. Precisely, that's right.  
 14 So if it's a document that  
 15 another company used, we couldn't blame  
 16 Allergan for that document, right?

17 MR. ARBITBLIT: Objection.  
 18 Argumentative. Calls for a legal  
 19 conclusion.

20 THE WITNESS: So Kadian  
 21 marketing overview with sales  
 22 representative training in October  
 23 of 2011, after Allergan acquired  
 24 Kadian.

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1       QUESTIONS BY MR. STAMPFL:  
 2           Q.     Okay. Can you look at the  
 3     bottom of page 2 and top of page 3 in your  
 4     Appendix I?  
 5           Do you see that you're  
 6     referring to something called the Kadian  
 7     Learning System?

8           A.     Uh-huh.  
 9           (Lembke Exhibit 25 marked for  
 10     identification.)

11      QUESTIONS BY MR. STAMPFL:  
 12     Q.     And I'm going to mark that  
 13     document now as Exhibit 25.

14     Q.     Okay. Doctor, I've handed you  
 15     Exhibit 25.

16     Q.     Is that the document that  
 17     you're referring to in your Appendix I.E?

18     A.     Yes, it appears to be that  
 19     document.

20     Q.     And do you see that on the very  
 21     face of -- can you see that on the very face  
 22     of that document it indicates it's not an  
 23     Allergan or an Actavis document, but rather  
 24     an Alpharma document?

25     A.     Yes, I do see that.

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1       Q.     And this is one of the five  
 2     documents you considered in part of forming  
 3     your opinions about Allergan, right?  
 4       A.     Yes.  
 5       Q.     So really there are only, at  
 6     most, four documents that were actually  
 7     Allergan documents that you considered,  
 8     right?

9           MR. ARBITBLIT: Object to form.  
 10     Calls for a legal conclusion.

11     Argumentative.

12     THE WITNESS: My understanding  
 13     was that these were all Allergan  
 14     documents.

15      QUESTIONS BY MR. STAMPFL:

16     Q.     Though this one says on its  
 17     face it's an Alpharma document, right?

18       MR. ARBITBLIT: Object to form.  
 19     THE WITNESS: It does say that  
 20     on the face.

21      QUESTIONS BY MR. STAMPFL:

22     Q.     Did you review these documents  
 23     before you wrote your report?

24       A.     Yes.

25       MR. STAMPFL: I will concede my

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1       time and pass the witness. Thank you.  
 2       THE WITNESS: You're welcome.

3       VIDEOGRAPHER: We're now going  
 4     off the record, and the time is

5     4:36 p.m.

6       (Off the record at 4:36 p.m.)

7       VIDEOGRAPHER: We are now going  
 8     back on the record, and the time is

9     4:47 p.m.

10      CROSS-EXAMINATION

11      QUESTIONS BY MS. VICARI:

12     Q.     Good afternoon, Dr. Lembke. My  
 13     name is Angela Vicari, and I am with the law  
 14     firm of Arnold and Porter, and I represent  
 15     Endo Pharmaceuticals, Inc., The Health  
 16     Solutions, Inc., and I also represent Par  
 17     Pharmaceutical, Inc., in this case.

18     Dr. Lembke, your report makes  
 19     no reference to Par, so you're not offering  
 20     any opinions in this case as to Par  
 21     Pharmaceutical, correct?

22       MR. ARBITBLIT: Objection.

23       Calls for a legal conclusion.

24       THE WITNESS: So one thing that  
 25     I am not aware of is the various

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1       acquisitions of one company by  
 2     another.

3       So maybe you could clarify for  
 4     me is -- was Par acquired by Endo? I  
 5     can't really speak to that. I can  
 6     speak to my knowledge of the actions  
 7     of Endo based on the documents that I  
 8     have reviewed and my broader knowledge  
 9     of the causality in the opioid  
 10     epidemic.

11      QUESTIONS BY MS. VICARI:

12     Q.     Are you aware of any  
 13     promotional activities by Par Pharmaceutical,  
 14     Inc.?

15     A.     What opioid does Par  
 16     Pharmaceutical, Inc., manufacture?

17     Q.     Sitting here today, you don't  
 18     know what opioids Par Pharmaceutical, Inc.,  
 19     manufactures, correct?

20     A.     No.

21     Q.     And if you don't know what  
 22     pharmaceutical medications Par

23     Pharmaceutical, Inc., makes, you can't make  
 24     any -- you can't issue any opinions to a  
 25     reasonable degree of medical certainty about

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1 any marketing or promotional activities that  
 2 Par engaged in, correct?  
 3 MR. ARBITBLIT: Object to form.  
 4 Legal conclusion.  
 5 THE WITNESS: I haven't  
 6 reviewed specific promotional  
 7 documents for Par Pharmaceuticals.  
 8 QUESTIONS BY MS. VICARI:  
 9 Q. Dr. Lemke, do you recall ever  
 10 prescribing Opana to a patient?  
 11 A. I don't specifically recall  
 12 prescribing Opana, but I may have done over  
 13 the years.  
 14 Q. Okay. Do you recall  
 15 prescribing original Opana ER to a patient?  
 16 A. I may have done, but I don't  
 17 recall specifically prescribing that.  
 18 Q. Do you recall prescribing a  
 19 reformulated Opana ER to a patient?  
 20 A. I don't have a specific  
 21 recollection.  
 22 Q. And do you recall ever  
 23 prescribing Percocet to a patient?  
 24 A. I don't have a specific  
 25 recollection of prescribing a specific opioid

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1 over the years.  
 2 Q. Do you have a recollection of  
 3 prescribing any other Endo opioid medications  
 4 to a patient?  
 5 A. No.  
 6 Q. In your opinion, have you ever  
 7 prescribed an Endo opioid where an opioid was  
 8 not medically necessary?  
 9 A. So in my opinion, the practice  
 10 of prescribing opioids for the treatment of  
 11 chronic pain is not evidence-based and,  
 12 therefore, not medically necessary.  
 13 Q. Okay. Thank you.  
 14 My question was: Have you ever  
 15 prescribed an Endo opioid where it was not  
 16 medically necessary?  
 17 A. I don't have a specific  
 18 recollection of prescribing Endo, so I can't  
 19 speak to the medical necessity.  
 20 Q. Dr. Lemke, are you aware of  
 21 any doctors who have safely and effectively  
 22 prescribed opioids to treat chronic pain?  
 23 MR. ARBITBLIT: Object to form.  
 24 THE WITNESS: I am aware of  
 25 lots of doctors who claim that their

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1 prescribing of opioids in the  
 2 treatment of chronic pain is  
 3 effective, but I believe that they  
 4 have been misinformed and do not fully  
 5 appreciate the risks involved.  
 6 QUESTIONS BY MS. VICARI:  
 7 Q. Do you believe that there is a  
 8 way for doctors to safely and prescribe --  
 9 strike that.  
 10 Is there a way for doctors to  
 11 safely and effectively prescribe opioids to  
 12 treat chronic pain?  
 13 MR. ARBITBLIT: Object to form.  
 14 THE WITNESS: I think there may  
 15 be rare exceptions in which that's  
 16 true, but for the vast majority of  
 17 patients, I don't believe that opioids  
 18 for chronic pain are either safe or  
 19 effective, and nor is it supported by  
 20 the evidence.  
 21 QUESTIONS BY MS. VICARI:  
 22 Q. You're not saying that the  
 23 prescription of opioids for the treatment of  
 24 chronic pain is malpractice, are you?  
 25 MR. ARBITBLIT: Object to form.

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1 THE WITNESS: I'm not saying  
 2 it's malpractice. In fact, I would  
 3 say that doctors have been duped and  
 4 so are not responsible for the ways in  
 5 which they have been prescribing,  
 6 despite the lack of evidence to  
 7 support the use of opioids in the  
 8 treatment of chronic pain.  
 9 QUESTIONS BY MS. VICARI:  
 10 Q. And do you believe that even  
 11 as -- sitting here today --  
 12 MR. ARBITBLIT: Object to form.  
 13 QUESTIONS BY MS. VICARI:  
 14 Q. -- it's currently being  
 15 prescribed?  
 16 MR. ARBITBLIT: Object to form.  
 17 THE WITNESS: I believe that  
 18 there are physicians who continue to  
 19 lack a full understanding of the  
 20 evidence regarding benefit and risks  
 21 of opioids in the treatment of chronic  
 22 pain.  
 23 QUESTIONS BY MS. VICARI:  
 24 Q. What steps can a doctor take to  
 25 safely and effectively prescribe opioids to

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1 treat chronic pain?  
 2 MR. ARBITBLIT: Object to form.  
 3 Argumentative. Assumes facts not in  
 4 evidence. Misstates the testimony.

5 THE WITNESS: Yeah, so your  
 6 question assumes that opioids are an  
 7 effective treatment for chronic pain,  
 8 and the evidence doesn't support that.

9 QUESTIONS BY MS. VICARI:

10 Q. Is every prescription of  
 11 opioids written for chronic noncancer pain  
 12 not medically necessary?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: There's no  
 15 evidence to support the benefit of  
 16 opioids in the treatment of chronic  
 17 pain.

18 QUESTIONS BY MS. VICARI:

19 Q. Is it your opinion that Endo's  
 20 engaging in misleading promotion of opioids  
 21 today?

22 MR. ARBITBLIT: Object to form.

23 THE WITNESS: I believe that  
 24 the problem of the defendants  
 25 manipulating and misrepresenting the

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1 evidence to promote opioid prescribing  
 2 is a problem that continues to this  
 3 day.

4 QUESTIONS BY MS. VICARI:

5 Q. Okay. That wasn't my question.  
 6 My question was very specific to Endo.  
 7 Is it your opinion that Endo is  
 8 engaging in misleading promotion of opioids  
 9 today?

10 A. Yes.

11 Q. Okay. And is it your opinion  
 12 is that Endo is miseducating doctors, even  
 13 today?

14 A. Yes.

15 Q. What is your basis for saying  
 16 that Endo is engaging -- or that Endo is  
 17 engaging in misleading promotion of opioids  
 18 today?

19 A. I believe that the defendants  
 20 still fail to acknowledge the weight of the  
 21 evidence that is insufficient and weak with  
 22 regards to the use of opioids in the  
 23 treatment of chronic pain, and still fail to  
 24 recognize the very high risk of addiction,  
 25 even when patients are prescribed opioids by

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1 a doctor for the treatment of chronic pain.  
 2 Q. Can you tell me what  
 3 promotional activities Endo is engaged in  
 4 today?

5 A. I believe that the false  
 6 messaging that is in my report continues  
 7 generally today.

8 Q. My question was very specific  
 9 to Endo.

10 Q. Can you tell me what  
 11 promotional activities Endo is engaged in  
 12 today?

13 A. I think that the extent of the  
 14 impact of the defendants' false messaging is  
 15 so profound and wide-reaching that in order  
 16 to really constitute an end to that false  
 17 messaging, it would require opioid  
 18 manufacturers to come out and boldly  
 19 acknowledge the ways in which they have  
 20 falsely promoted those messages and work to  
 21 correct those false statements and false  
 22 marketing.

23 Q. And failure to do so, in my  
 24 opinion, constitutes continued implicit  
 25 marketing of older messages.

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1 Q. So the marketing you're talking  
 2 about today is implicit marketing?  
 3 A. Much of it is covert and  
 4 implicit, and that's one of the major  
 5 arguments that I make in my report is the way  
 6 that opioid manufacturers have infiltrated  
 7 key opinion leaders and watchdog  
 8 organizations inside of medicine to give the  
 9 impression that these marketing messages are  
 10 based in science, when, in fact, that's not  
 11 the case.

12 Q. Dr. Lembke, all the documents  
 13 that you considered in forming your opinions  
 14 as to Endo are set forth in Exhibit B to your  
 15 report and in the supplement that plaintiffs'  
 16 counsel I believe sent to defense counsel on  
 17 April 22nd; is that correct?

18 A. Yes.

19 Q. Okay. You didn't consider any  
 20 deposition testimony given by Endo witnesses,  
 21 did you?

22 A. No.

23 Q. And you didn't consider any  
 24 deposition testimony given by Par witnesses,  
 25 did you?

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1 A. No.  
 2 Q. And you didn't review all of  
 3 Endo's marketing materials, did you?  
 4 A. No.  
 5 Q. And you didn't consider all of  
 6 Endo's marketing materials in issuing your  
 7 opinions in this case, correct?  
 8 A. That's correct.  
 9 Q. And you're not offering an  
 10 opinion on Endo marketing materials that  
 11 aren't listed in Exhibit B to your report or  
 12 in the supplement that we received from  
 13 plaintiffs' counsel, correct?  
 14 A. That's correct.  
 15 Q. And you're not offering an  
 16 opinion on any studies that were sponsored by  
 17 Endo that aren't listed in Exhibit B to your  
 18 report or in the 4/22 supplement that we  
 19 received from plaintiffs' counsel, correct?  
 20 MR. ARBITBLIT: Include -- are  
 21 you including what she's mentioned in  
 22 her report itself?  
 23 MS. VICARI: Well, if it's in  
 24 her report, she considered it, and  
 25 it's in Exhibit B. Correct, Counsel?

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1 MR. ARBITBLIT: Yes.  
 2 MS. VICARI: You know what?  
 3 I'm talking about Exhibit B. I'll  
 4 repeat my question.  
 5 QUESTIONS BY MS. VICARI:  
 6 Q. You're not offering an opinion  
 7 on any studies that were sponsored by Endo  
 8 that aren't listed in Exhibit B or in the  
 9 4/22 supplement?  
 10 A. That's correct.  
 11 Q. And you're not offering an  
 12 opinion on any statements by Endo that aren't  
 13 in documents that are listed in Exhibit B or  
 14 in the 4/22 supplement, correct?  
 15 A. That's correct.  
 16 Q. And all the opinions that you  
 17 intend to offer at trial are included in your  
 18 report, correct?  
 19 A. Yes, unless there are  
 20 additional documents that you would like me  
 21 to review. I would be happy to do that.  
 22 Q. You don't intend to offer  
 23 opinions at trial that aren't in your report,  
 24 correct?  
 25 A. That's correct.

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1 Q. Now, you in appendix -- in the  
 2 appendix of your report, you have a five-page  
 3 section in which you refer to Endo  
 4 Pharmaceuticals, correct?  
 5 I believe it's Exhibit 13?  
 6 A. Yes.  
 7 Q. Okay. And in those five pages,  
 8 Section 1.D, you cite several Endo documents  
 9 and studies, correct?  
 10 A. I'm not finding 1.D.  
 11 Q. If you hand me Exhibit 13, I  
 12 had left it open on your stack of exhibits  
 13 next to you.  
 14 A. Oh, I see, yes. I do see that,  
 15 the D.  
 16 Q. Exhibit 13, Section 1.D,  
 17 correct?  
 18 A. Yes, I was looking at the  
 19 letters.  
 20 Q. And in those five pages, we'll  
 21 call it the Endo section of your report, you  
 22 cite several Endo documents and studies,  
 23 correct?  
 24 A. That's right.  
 25 Q. Can you identify any doctors in

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1 Cuyahoga and Summit County who actually read  
 2 the documents you cite in those pages of your  
 3 report?  
 4 MR. ARBITBLIT: Object to form.  
 5 THE WITNESS: I cannot cite  
 6 specific doctors, but this was a  
 7 wide-ranging campaign on the part of  
 8 Endo and other defendants, so I'm  
 9 confident that providers in Summit and  
 10 Cuyahoga County were exposed to this  
 11 false messaging.  
 12 QUESTIONS BY MS. VICARI:  
 13 Q. My question wasn't about false  
 14 messaging generally. Very specific question.  
 15 You can't identify any doctors  
 16 in Cuyahoga or Summit County who read the  
 17 documents that you cite on those five pages  
 18 of your report?  
 19 MR. ARBITBLIT: Objection.  
 20 Argumentative.  
 21 THE WITNESS: I can't cite  
 22 specific doctors.  
 23 QUESTIONS BY MS. VICARI:  
 24 Q. And you can't cite specific  
 25 doctors who relied on any of the specific

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1 documents that you cite in those five pages  
 2 of your report, correct?  
 3 A. I would be very surprised if  
 4 doctors in Cuyahoga and Summit Counties had  
 5 not been exposed to this misleading marketing  
 6 as it was a national campaign, and we were  
 7 all exposed to it, and it caused the paradigm  
 8 shift that changed the way that opioids are  
 9 prescribed in this country.

10 Q. Thank you, Doctor.

11 I was talking about the  
 12 specific documents that you cite in those  
 13 five pages.

14 A. Uh-huh.

15 Q. You can't identify any doctors  
 16 in Cuyahoga or Summit County who relied on  
 17 those documents that you cite in those five  
 18 pages of your report, correct?

19 MR. ARBITBLIT: Objection.

20 Objection. Argumentative. Misstates.

21 THE WITNESS: I feel like I  
 22 answered the question to the best of  
 23 my ability.

24 QUESTIONS BY MS. VICARI:

25 Q. You can't say that any patient

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1 in Summit or Cuyahoga County who was  
 2 prescribed an Endo opioid medication would  
 3 not have been prescribed a different opioid  
 4 if Endo did not market opioids, correct?

5 A. Oh, can you rephrase that?

6 Sorry.

7 Q. You can't say that any patient  
 8 in Summit or Cuyahoga County who was  
 9 prescribed an Endo opioid would not otherwise  
 10 have been prescribed an opioid if Endo did  
 11 not market opioid products?

12 MR. ARBITBLIT: Objection.

13 Speculative.

14 THE WITNESS: I guess I'm going  
 15 to ask you to rephrase the question.  
 16 I'm having trouble understanding it.

17 QUESTIONS BY MS. VICARI:

18 Q. Patients in Summit and Cuyahoga  
 19 Counties were prescribed opioids?

20 A. Correct.

21 Q. And some were prescribed Endo  
 22 opioids, correct?

23 A. Yes.

24 Q. And if Endo opioids weren't  
 25 available to those patients, you can't say

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1 that those patients would not have otherwise  
 2 been prescribed a different opioid product,  
 3 correct?

4 MR. ARBITBLIT: Objection.

5 Speculative.

6 THE WITNESS: It's hard for me  
 7 to know if they hadn't been prescribed  
 8 Endo, whether or not they would have  
 9 been prescribed some other opioid.

10 QUESTIONS BY MS. VICARI:

11 Q. It depends on the individual  
 12 patient and the individual doctor, correct?

13 MR. ARBITBLIT: Object to form.

14 THE WITNESS: Again, it's very  
 15 hard for me to speculate on that type  
 16 of scenario.

17 QUESTIONS BY MS. VICARI:

18 Q. You would be speculating  
 19 because it's an individualized inquiry,  
 20 right?

21 MR. ARBITBLIT: Object to form.

22 Misstates.

23 QUESTIONS BY MS. VICARI:

24 Q. You can answer the question.

25 A. Can you rephrase it?

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1 Q. I said you would be speculating  
 2 because it's an individualized inquiry,  
 3 correct?

4 MR. ARBITBLIT: Object to form.

5 THE WITNESS: Can you rephrase  
 6 your question? Sorry.

7 QUESTIONS BY MS. VICARI:

8 Q. You would be speculating  
 9 because it depends on the patient, right?

10 MR. ARBITBLIT: Object to form.

11 THE WITNESS: I think it's just  
 12 speculative, and so it's hard for me  
 13 to answer.

14 QUESTIONS BY MS. VICARI:

15 Q. You would agree with me that  
 16 there are nonopioid medications that can  
 17 treat pain, right?

18 A. Yes.

19 Q. Okay. And you would agree with  
 20 me that all medications are accompanied with  
 21 risks of some sort?

22 A. Yes.

23 Q. Okay. And acetaminophen is a  
 24 drug that can be used to treat pain, correct?

25 A. Yes.

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1 Q. And but you would agree with me  
 2 that treatment with acetaminophen is not  
 3 appropriate in all patients, right?  
 4 A. Yes.

5 Q. And you would agree with me  
 6 that treatment with NSAIDs is not appropriate  
 7 in all patients, right?

8 A. Yes.

9 Q. Dr. Lemke, you don't have an  
 10 opinion about whether Endo violated any FDA  
 11 regulations concerning pharmaceutical  
 12 marketing, correct?

13 A. There are other experts who  
 14 will testify regarding the FDA. I was not  
 15 asked to provide an opinion on that.

16 Q. Dr. Lemke, on page 55 of your  
 17 report, you cite a study by McIlwain, and you  
 18 note that Endo sponsored that study.

19 My only question to you is  
 20 whether you can identify any physicians in  
 21 Summit or Cuyahoga County who read the  
 22 McIlwain study?

23 MR. ARBITBLIT: Object to form.  
 24 THE WITNESS: I can't speak to  
 25 individual physicians, but I do think

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1 that the Cochrane analysis had a huge  
 2 impact on physicians' perception of  
 3 risk --

## 4 QUESTIONS BY MS. VICARI:

5 Q. I didn't ask about the Cochrane  
 6 analysis. I have limited time. I asked  
 7 about the McIlwain study.

8 MR. ARBITBLIT: Limited time or  
 9 not, Counsel, you're supposed to let  
 10 her finish.

11 THE WITNESS: I think I did  
 12 answer it.

## 13 QUESTIONS BY MS. VICARI:

14 Q. You can't identify any  
 15 physicians, correct?

16 MR. ARBITBLIT: Object to form.

17 THE WITNESS: Again, I think  
 18 that I've answered this before in  
 19 other ways, with other defendants  
 20 asking similar questions, that  
 21 although I don't -- I can't identify  
 22 any specific physicians. Broadly this  
 23 is misleading marketing messages. We  
 24 were all exposed to them in the '90s  
 25 and ongoing to today.

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1 And it had a significant and  
 2 instrumental effect on the way that we  
 3 prescribe opioids.

## 4 QUESTIONS BY MS. VICARI:

5 Q. Dr. Lemke, you would agree  
 6 with me that as a general matter, a patient's  
 7 exposure to an ineffective medical treatment  
 8 should be minimized, correct?

9 MR. ARBITBLIT: Object to form.  
 10 Incomplete hypothetical.

11 THE WITNESS: It says here --  
 12 can you restate because it says  
 13 "shouldn't be minimized." But I think  
 14 you meant should be minimized.

## 15 QUESTIONS BY MS. VICARI:

16 Q. That is a mistake in the  
 17 transcript.

18 You would agree with me that a  
 19 patient's exposure to an ineffective medical  
 20 treatment should be minimized?

21 MR. ARBITBLIT: Object to form.

22 THE WITNESS: I do agree with  
 23 that.

24 MS. VICARI: Thank you. I have  
 25 no further questions. We can go off

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1 the record. I'll pass the witness.

2 VIDEOGRAPHER: We're now going  
 3 off the record, and the time is  
 4 5:07 p.m.

5 (Off the record at 5:07 p.m.)

6 VIDEOGRAPHER: We're now going  
 7 back on the record, and the time is  
 8 5:08 p.m.

## 9 CROSS-EXAMINATION

## 10 QUESTIONS BY MS. HOLLY:

11 Q. My name is Pam Holly. I'm an  
 12 attorney with Morgan Lewis, and we represent  
 13 Teva Pharmaceuticals, USA, Cephalon, Inc.,  
 14 Actavis Pharma, Watson Laboratories and  
 15 Actavis, LLC.

16 Are you familiar -- or are you  
 17 aware that Watson Laboratories is a party to  
 18 this action?

19 A. I was not aware.

20 Q. Is it fair to say that you  
 21 don't know what opioid medications they sell?

22 A. I know what opioids Teva  
 23 Pharmaceuticals sells, so if that's all part  
 24 of the same entity, Actiq and Fentora.

25 Q. So is it fair to say that you

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1 don't know what opioids Watson Labs sells,  
 2 correct?  
 3 A. Correct.  
 4 Q. Are you aware that Actavis  
 5 Pharma is a part of this litigation?  
 6 A. I believe that Actavis Pharma  
 7 was mentioned in combination with Allergan.  
 8 Q. A different entity, not Actavis  
 9 Pharma.  
 10 A. Okay. Okay.  
 11 Q. So it's fair to say that you're  
 12 not aware that Actavis Pharma is a party to  
 13 this litigation?  
 14 A. It's fair to say that I'm not  
 15 aware of the various mergers, and it is very  
 16 confusing. So I'm not entirely aware of who  
 17 owned what when.  
 18 Q. Are you aware that Actavis,  
 19 LLC, is a party to this litigation?  
 20 A. I wasn't aware, but I am aware  
 21 now.  
 22 Q. Are you aware of what opioid  
 23 medications they sell?  
 24 A. No.  
 25 Q. Are you aware that generic

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1 manufacturers do not -- excuse me, do not  
 2 market their products?  
 3 A. I wasn't specifically aware of  
 4 that, no.  
 5 Q. Are you aware that Teva  
 6 Pharmaceuticals USA is a party to this  
 7 litigation?  
 8 A. Yes.  
 9 Q. Do you know what products Teva  
 10 Pharmaceuticals --  
 11 A. Actiq and Fentora.  
 12 Q. Your report makes no reference  
 13 to Teva Pharmaceuticals USA, so it's fair to  
 14 say that you can't offer an opinion to a  
 15 reasonable degree of medical certainty about  
 16 the marketing of Teva USA; is that correct?  
 17 A. I disagree. If they're named  
 18 in the complaint, and I see all the  
 19 defendants as party to the litigation, and --  
 20 Q. Any -- pardon me.  
 21 A. Go ahead. Go ahead.  
 22 Q. I was going to ask you to point  
 23 me to a reference in your report to Teva  
 24 Pharmaceuticals USA.  
 25 We may have to go off the

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1 record, but I only have five minutes.  
 2 A. Sorry. Yeah. There's no  
 3 specific reference in my report to Teva  
 4 Pharmaceuticals, but if they're named in the  
 5 complaint, I believe -- I agree with the  
 6 complaint, and my report applies to all the  
 7 defendants in particular as pertains to the  
 8 misrepresentation of the benefits and risks  
 9 of opioids more broadly as a class of drugs.  
 10 Q. So Appendix I of your report  
 11 has five sections, correct?  
 12 A. Yes.  
 13 Q. And none of those five sections  
 14 relate to Teva Pharmaceuticals or Cephalon,  
 15 correct?  
 16 A. That's correct.  
 17 Q. So it's fair to say that in  
 18 your report, you're not offering an opinion  
 19 in this litigation about the marketing  
 20 conducted by those entities, correct?  
 21 A. No. I feel like I answered  
 22 that question already.  
 23 Q. Well, I don't -- I disagree  
 24 with all due respect.  
 25 There's no section -- what is

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1 the title of Appendix I?  
 2 A. Appendix I?  
 3 Q. In the table of contents, you  
 4 refer to it as misleading promotional  
 5 messages, correct?  
 6 A. Yes.  
 7 MR. ARBITBLIT: That's it.  
 8 Thank you, Counsel. It's been nice.  
 9 Feel free to take whatever is left  
 10 over at the end, sandwiches, I mean.  
 11 VIDEOGRAPHER: Shall we  
 12 conclude?  
 13 MR. ARBITBLIT: Yes.  
 14 VIDEOGRAPHER: Okay. This  
 15 concludes the video deposition of Anna  
 16 Lembke. We are --  
 17 MS. HOLLY: I'm sorry, I did  
 18 not have five minutes.  
 19 MS. DO AMARAL: You did.  
 20 MS. HOLLY: I did not have five  
 21 minutes.  
 22 VIDEOGRAPHER: I have five.  
 23 MS. HOLLY: I am --  
 24 MR. ARBITBLIT: What does your  
 25 timer say, Pam? Have you timed

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1 yourself?

2 MS. HOLLY: Yeah, my time is

3 three minutes.

4 MS. DO AMARAL: No. No, sorry.

5 MR. ARBITBLIT: No.

6 MS. DO AMARAL: Your

7 codefendants, the videographer, and by

8 my count --

9 MS. HOLLY: All right. I'm

10 going to state for the record that I

11 have specific time to ask questions

12 that I intended to ask on behalf of my

13 clients, and I object and don't agree

14 to close the deposition, and I reserve

15 all rights to raise with the Court to

16 request the appropriate relief,

17 including any deposition testimony

18 that went unanswered here today.

19 MR. ARBITBLIT: Well, let's do

20 two more minutes, Pam, and ask your

21 questions. Let's not fight about two

22 minutes.

23 MS. HOLLY: Okay. Well, then I

24 need -- I need -- I need full two

25 minutes.

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1 MR. ARBITBLIT: Calm down.

2 MS. HOLLY: I need some answers

3 within that time, please.

4 MR. ARBITBLIT: Well, we're not

5 going to give you answers just to give

6 you answers. If you ask questions,

7 the witness will answer them.

8 MS. HOLLY: I'm not going to

9 waste time talking about this. I made

10 my objection, and I'm going to

11 continue my examination.

12 MR. ARBITBLIT: This is not

13 your two minutes. This is discussion

14 about you're claiming that she's not

15 answering your questions, which I

16 disagree. Start your two minutes and

17 ask your questions.

18 QUESTIONS BY MS. HOLLY:

19 Q. Are you aware of any marketing

20 statements made by Teva or Cephalon in Summit

21 or Cuyahoga County?

22 A. I'm not specifically aware of

23 marketing specifically in those counties, but

24 I believe that the misleading promotional

25 statements have disseminated across every

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1 region of the United States, and that

2 Cuyahoga County and Summit County are not

3 exceptions to that.

4 Q. And what are the misleading

5 statements made by -- contained in your

6 report -- in your opinion in your report by

7 Cephalon and Teva?

8 A. If they were named in the

9 complaint, and they were, then they

10 participated in the misleading marketing that

11 overstated the benefits and understated the

12 risks.

13 Q. So your opinion then is based

14 on the complaint allegations as opposed to

15 underlying evidence or documents?

16 MR. ARBITBLIT: Object to form.

17 THE WITNESS: My complaint is

18 based on my understanding of the ways

19 in which opioid manufacturers across

20 the board, including all of the

21 defendants named in the complaint,

22 misrepresented the evidence.

23 QUESTIONS BY MS. HOLLY:

24 Q. But Exhibit {inaudible} does

25 not contain any documents produced by Teva or

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1 Cephalon, correct?

2 A. Pardon me?

3 Q. Exhibit -- your report does not

4 contain any documents produced by Teva or

5 Cephalon; is that correct?

6 A. I do not have a section in my

7 appendix on Teva or Cephalon.

8 Q. So what is the basis of your

9 opinion as it relates to Teva and Cephalon if

10 you have nothing in your report that relates

11 to them?

12 A. I was the recipient of

13 marketing for products made by Teva,

14 including Actiq and Fentora, in my medical

15 training and residency, so I don't need to

16 review specific documents. I've been hearing

17 those messages for two decades.

18 MR. ARBITBLIT: And that was

19 over two minutes, and we're done.

20 MS. HOLLY: I renew my

21 objection to the time.

22 MR. ARBITBLIT: Take it up with

23 your co-counsel. Take it up with your

24 defense counsel. They divided the

25 time.

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1                   VIDEOGRAPHER: Okay. We are  
 2                   now concluding the video deposition of  
 3                   Anna Lembke. We are now going off the  
 4                   record, and the time is 5:17 p.m.  
 5                   (Deposition concluded at 5:17 p.m.)  
 6                   - - - - -

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1                   CERTIFICATE  
 2  
 3                   I, CARRIE A. CAMPBELL, Registered  
 4                   Diplomate Reporter, Certified Realtime  
 5                   Reporter and Certified Shorthand Reporter, do  
 6                   hereby certify that prior to the commencement  
 7                   of the examination, Anna Lembke, M.D., was  
 8                   duly sworn by me to testify to the truth, the  
 9                   whole truth and nothing but the truth.  
 10                  I DO FURTHER CERTIFY that the  
 11                  foregoing is a verbatim transcript of the  
 12                  testimony as taken stenographically by and  
 13                  before me at the time, place and on the date  
 14                  hereinbefore set forth, to the best of my  
 15                  ability.

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*Carrie A. Campbell*

CARRIE A. CAMPBELL,  
 NCRA Registered Diplomate Reporter  
 Certified Realtime Reporter  
 Notary Public  
 Dated: April 29, 2019

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1                   INSTRUCTIONS TO WITNESS  
 2  
 3                   Please read your deposition over  
 4                   carefully and make any necessary corrections.  
 5                   You should state the reason in the  
 6                   appropriate space on the errata sheet for any  
 7                   corrections that are made.

8                   After doing so, please sign the  
 9                   errata sheet and date it. You are signing  
 10                  same subject to the changes you have noted on  
 11                  the errata sheet, which will be attached to  
 12                  your deposition.

13                  It is imperative that you return  
 14                  the original errata sheet to the deposing  
 15                  attorney within thirty (30) days of receipt  
 16                  of the deposition transcript by you. If you  
 17                  fail to do so, the deposition transcript may  
 18                  be deemed to be accurate and may be used in  
 19                  court.

20

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1                   ACKNOWLEDGMENT OF DEPONENT  
 2  
 3  
 4                   I, \_\_\_\_\_, do  
 5                   hereby certify that I have read the foregoing  
 6                   pages and that the same is a correct  
 7                   transcription of the answers given by me to  
 8                   the questions therein propounded, except for  
 9                   the corrections or changes in form or  
 10                  substance, if any, noted in the attached  
 11                  Errata Sheet.

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Anna Lembke, M.D.

DATE

Subscribed and sworn to before me this  
 \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_\_.  
 My commission expires: \_\_\_\_\_

Notary Public

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LAWYER'S NOTES	
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